Chapter 2

Medicines

The medicines sector has enormous economic and social implications for Mexico. It is an important source of employment (367 056 people, as of 2013) and contributor of GVA (from 2005 until 2015, the GVA for medicine manufacturing was, on average, 0.67% of total GDP). Among its main constraints are a lack of regulation concerning pecuniary advantages pharmaceutical companies can provide to doctors; patients' restricted possibilities to substitute branded medicines for generics; a regulatory model of maximum prices for patented medicines that leads to high prices for Mexican consumers; the confidentiality of the amendment to the medicines-pricing agreement; and provisions that allow the sector's regulators unguided discretion. In addition, several dispositions discriminate against foreigners, in both the private and the public sectors. The report also finds various Mexican standards that expressly state that they are not in line with international norms.

2.1. Economic overview of the medicines sector

2.1.1. Definition of the subsectors and main concepts

This report analyses the medicine sector and covers the manufacture, wholesale, and retail of medicines. The investigation does not cover industrial-use alcohols; equipment for medical and dental use and for laboratories; disposable supplies for medical use; ophthalmic items; optical goods and orthopaedic items.[1]

According to the Mexican General Health Law,[2] a medicine is "every substance or mix of substances of natural or synthetic origin with a therapeutic, preventive or rehabilitating effect, presented under a pharmaceutical form and identified like this owing to its pharmacological activity and to its physical, chemical and biological characteristics. In the case of a product with nutriments, it will be considered as a medicine whenever it refers to a preparation containing in an individual or associated way, vitamins, minerals, electrolytes, amino acids or fatty acids, in concentrations higher than natural food and if it is also presented in a defined pharmaceutical form and whose indications of usage include therapeutic, preventive or rehabilitating effects."[3]

The General Health Law classifies medicines according to their method of preparation and nature.[4] Under Mexican law, "generics" are medicines that can be used instead of original patent medicines once there is proof that their characteristics (e.g. pharmaceutical form, active substance, route of administration) are identical to the reference medicine.[5] Since 2011, the Federal Commission for the Protection Against Sanitary Risk (Comisión Federal para la Protección contra Riesgos Sanitarios, COFEPRIS) has promoted the adoption of generics in Mexico. As a result, generics' market penetration has increased, both in terms of market value and volume. In 2010, about 30% of market value was made up of generics; by 2013, this percentage had increased to 52%. Similarly, in 2010, generics accounted for 54% of the market volume, while in 2013, they accounted for 84% (COFEPRIS, 2016).

Consumers in Mexico can purchase medicines with or without prescription. If sold without prescription, medicines are commonly known as "prescription-free medicines" or "over-the-counter" (OTC).

2.1.1.1. Price Regulation

Mexico has established a price-regulation mechanism that aims to protect consumers and prevent excessive pricing for patented medicines.[6] The Ministry of Economy, with the support of the Ministry of Health, approves maximum sale prices for medicines. In practice, only patented medicines are subject to price regulation; pharmaceutical companies set the prices of generics without regulation.

To determine the price of patented medicines, pharmaceutical companies submit their "selling reference prices" to the Ministry of Economy. The selling reference price is equal to the international reference price, which, in turn, is a weighted average of the medicine's ex-factory price in the six countries where the product enjoys the highest sales, plus the estimated (non-regulated) wholesale and retail mark-ups (OECD, 2008). The Ministry of Economy regularly publishes a list of patented medicines with their maximum prices.

2.1.1.2. Basic Formulary of Inputs, and Input Catalogue

The General Health Council (Consejo de Salubridad General), a collegial body of the Mexican government reporting directly to the President of Mexico, is mandated to issue the Basic Formulary of Inputs (Cuadro Básico de Insumos) for the first level of medical care.[7] Additionally, the General Health Council issues an Input Catalogue (Catálogo de Insumos) for the second and third levels.[8]

Public-sector institutions, mainly the Mexican Social Security Institute (Instituto Mexicano del Seguro Social, IMSS) for regular workers (*trabajadores formales*) and the Institute for Social Security and Services for State Workers (Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado, ISSSTE) for employees of federal and state governments,[9] can only buy medicines and inputs included in the Basic Formulary of Inputs or Input Catalogue.[10] In addition, professionals from public institutions are generally obliged to prescribe only medicines contained in these documents.[11]

2.1.1.3. Pharmacopoeia

The Mexican Pharmacopoeia determines the composition a product must possess in order to be considered as a medicine or as an input for a medicine. It provides the requirements for the identity, purity and quality of medicines, as well as general methods for their analysis, according to the Regulation on Health Inputs (Reglamento de Insumos para la Salud). In addition, the Mexican Pharmacopoeia and its supplements provide rules to all establishments[12] that are active in obtaining, processing, manufacturing, preparing, conserving, mixing, conditioning, packaging and handling medicines.[13] Finally, there are also Mexican Pharmacopoeia supplements that provide general rules for pharmacies.

The Ministry of Health, through the Permanent Commission for the Mexican Pharmacopoeia (Comisión Permanente de la Farmacopea de los Estados Unidos Mexicanos, CPFEUM), constantly updates the Mexican Pharmacopoeia. Complete new editions are issued every three to ten years, though annual updates are published as supplements. The current edition is the eleventh and was issued in 2014.[14] According to the Regulation on Health Inputs, other countries' pharmacopoeias can be used in place of the Mexican Pharmacopeia, if the latter does not provide the necessary information for allopathic, homeopathic or herbal medicines.

2.1.1.4. Regulatory scheme: sanitary authorisations and other certificates

In Mexico, sanitary authorisations (*autorizaciones sanitarias*; "sanitary" is here used in its sense "of or in relation to health") along the value chain of medicines are necessary in order to guarantee that medicines are risk-free for end consumers. Pharmaceutical companies must have a sanitary registry for every medicine they commercialise, which must be renewed every five years. The export of narcotics or psychotropic medicines requires a sanitary permit. Establishments engaged in the development, manufacture or preparation of medicines require a sanitary licence to operate.

According to the General Health Law, the Ministry of Health – through COFEPRIS – allows private companies that hold sanitary authorisations to trade in medicines. These include licences, permits and sanitary registries.

- **Sanitary licences (licencias sanitarias).** Companies require a sanitary licence to manufacture medicines. They are necessary for:

- establishments engaged in the development, manufacture or preparation of medicines
- establishments engaged in the manufacture of biotechnological products or their inputs.

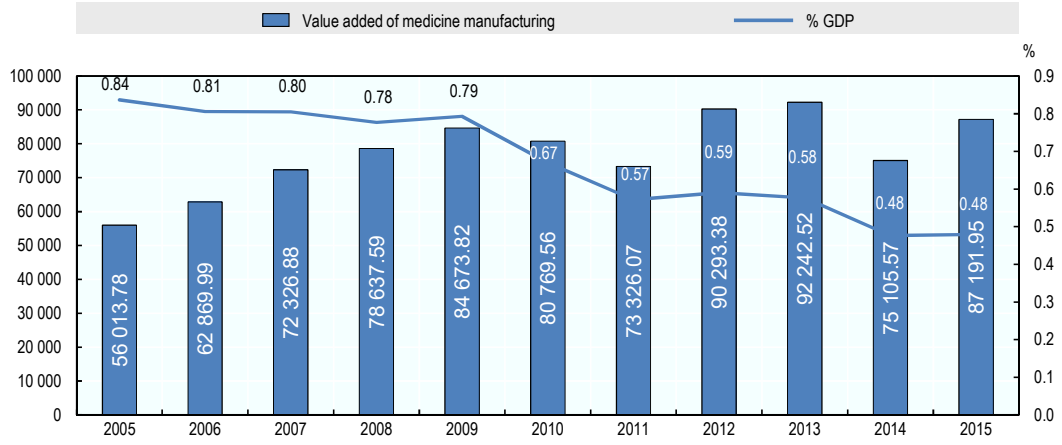
According to the General Health Law, the export of health inputs does not require a sanitary licence but rather an "export certificate" (*certificado de exportación*) issued by the Ministry of Health. If the exporter proves the buyer has accepted the medicine, it is not necessary to obtain a sanitary registry in addition to the export certificate.

- **Sanitary permits (permisos sanitarios).** A sanitary permit is mandatory for the following activities:
  - pharmacies possessing control books for narcotic drugs or psychotropic substances.
  - medical prescription of narcotics or psychotropic substances made by any of the following professionals: physicians; surgeons; veterinary doctors when drugs are prescribed for animals; dental surgeons and interns.
  - advertising related to medicines.
  - import of medicines, import and export of narcotics and psychotropic substances or products containing them.
- **Sanitary registries (registros sanitarios).** To be commercialised in Mexico, medicines, narcotics or psychotropic substances are required to obtain a sanitary registry (*registros sanitarios*), which is managed by the Ministry of Health. In order to obtain a sanitary registry, the Ministry of Health or Authorised Third Parties (Tercero Autorizado)[15] verify compliance of the products with best practice, and grant good manufacturing practice (GMP) certificates for health inputs. COFEPRIS issues such GMP certificates itself, which last 30 months; it also recognises eight foreign authorities as valid GMP issuers. COFEPRIS also confirms that the applicant has the necessary GMP certificates for all active substances in a medicine, even when these substances have been manufactured abroad. Mexican health authorities will recognise the foreign certification of active substances as long as there is an international treaty between Mexico and the country of origin.[16] In cases where a Mexican pharmaceutical manufacturer wants to buy substances from a supplier based in a country with no international treaty, COFEPRIS will send inspectors to certify the foreign supplier's plant. The Mexican producer is liable for the costs, including fees (MXN 84 080.88 for every visit) and travel expenses (the visits last at least five days and longer if more than one ingredient is involved).[17] Sanitary registries have to be renewed every five years.

2.1.2. Gross value added of the medicine manufacturing

From 2005 until 2015, the gross value added (GVA) for medicine manufacturing was, on average, 0.67% of total gross domestic product (GDP), peaking at 0.84% in 2005, before dropping to 0.48% by 2015. In total numbers, the GVA in 2015, measured in real terms, was MXN 87 192 million.

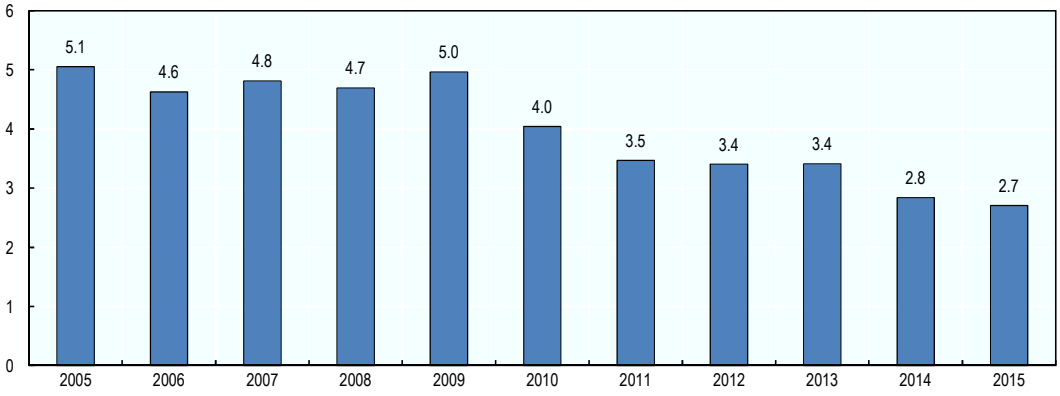
Figure 2.1. **Medicine manufacturing: GVA (2015 MXN, millions) and percentage of GDP, 2005-2015**



Source: INEGI, Banco de Información Económica, Sistema de Cuentas Nacionales de México

Medicine manufacturing's share of GVA as part of the manufacturing sector's total GVA steadily declined, except for 2009, from 5.1% in 2005 to 2.7% in 2015, averaging 4% during those years.

Figure 2.2**. Share of GVA (%) of medicine manufacture in manufacturing sector GVA, 2005-2015**



Source: INEGI, Banco de Información Económica, Sistema de Cuentas Nacionales de México

2.1.3. Market structure and main indicators

2.1.3.1. Manufacturing

Market participants

According to data from COFEPRIS, as of 17 March 2017, 241 different pharmaceutical companies held valid sanitary licenses for manufacturing medicines (allopathic and homeopathic) in Mexico, including nine that also manufactured raw materials. Additionally, 36 pharmaceutical companies only manufactured raw materials. The top ten leading pharmaceutical companies accounted for 42% of the medicine-manufacturing market (by value) in 2014, of which two were Mexican-owned companies (Laboratorios Sanfer and Laboratorios Senosiain).

Table 2.1. **Top 10 leading corporations by value in the total market (August 2014)**

Company	Country of origin	Market Share (%)
Pfizer	United States	6.4
Sanofi	France	5.7
Bayer	Germany	5.4
Novartis	Switzerland	4.6
Schering-Plough*	United States	4.4
Boehringer Ingelheim	Germany	3.8
Sanfer	**Mexico**	**3.2**
Merck-Serono	Germany	3.1
Johnson & Johnson	United States	3.0
Laboratorios Senosiain	**Mexico**	**3.0**

* In November 2009, Merck & Co., Inc. and Schering-Plough merged.
(see, www.sec.gov/Archives/edgar/data/310158/000089882209000096/pressrelease.htm).

The statistics in this table, from Healthcare Life Sciences & Review, still use the name Schering-Plough.

Source: *Healthcare Life Sciences & Review*, published by PharmaBoardroom in collaboration with CANIFARMA (November 2015), with data from IMS Health.

Table 2.2. **Top ten OTC pharmaceutical companies in Mexico, 2012**

Company	Country of origin	Market Share (%)
Bayer	Germany	8.7
Genomma Lab Internacional	**Mexico**	**8.7**
Merck & Co.	United States	5.8
Johnson & Johnson	United States	5
Procter & Gamble	United States	4.7
Boehringer Ingelheim	Germany	4.7
Laboratorios Pisa	**Mexico**	**4.7**
Bristol-Myers Squibb	United States	4.6
Sanofi	France	4.2
Novartis	Switzerland	3.7

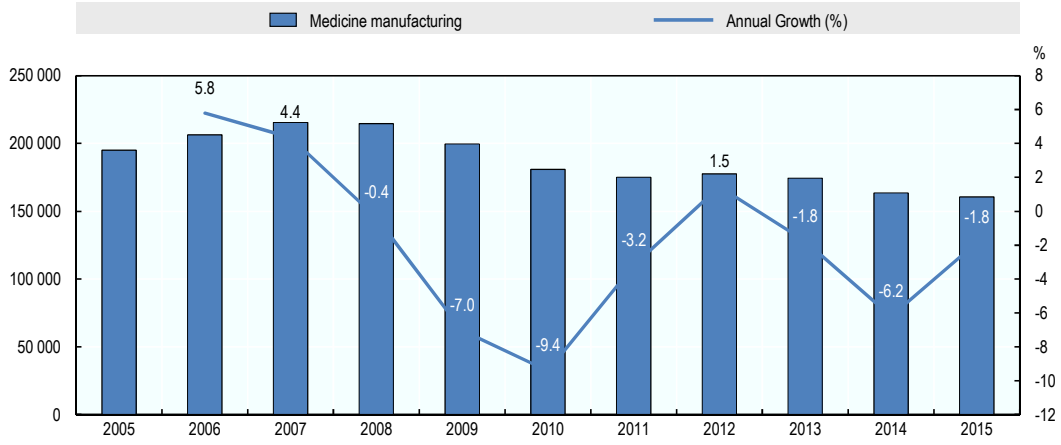
Source: PROMÉXICO, Unidad de Inteligencia de Negocios (2013), *Industria Farmacéutica*

For the manufacture of OTC products in Mexico, data from PROMÉXICO – a Mexican governmental body promoting foreign investment – put two Mexican firms in the top ten in 2012, with the caveat that recent data are not readily available.[18]

Manufacturing by value

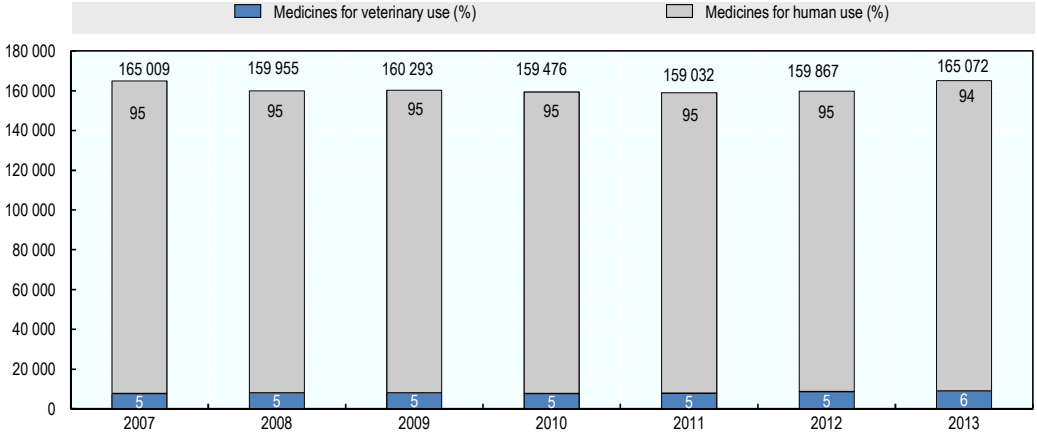
The manufacture of medicines in Mexico has declined steadily. From 2005 to 2015, according to INEGI, the value of medicine manufacturing, measured in real terms, decreased at an average annual rate of 1.9%. In 2015, medicine manufacturing in Mexico was worth MXN 160 588 million.

Figure 2.3. **Medicine manufacturing (2015 MXN, millions), 2005-2015**



Source: INEGI, Banco de Información Económica, Sistema de Cuentas Nacionales de México

Figure 2.4. **Ex-factory sales of medicines for human and veterinary use (2015 MXN, millions), 2007-2013**

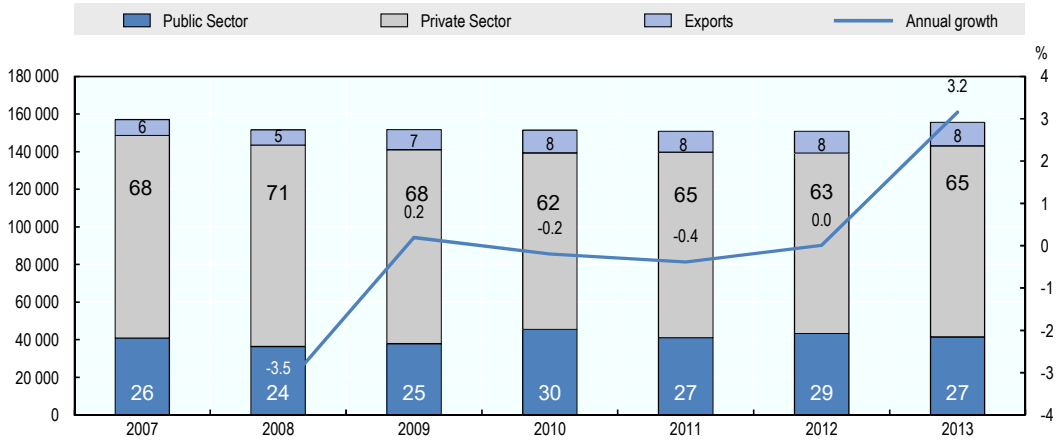


Source: CANIFARMA (2015), *Compendio Estadístico de la Industria Farmacéutica en México (2007-2013)*

According to pharmaceutical-industry body CANIFARMA, in 2013, its members' ex-factory sales accounted for MXN 165 072 million in real terms, which includes the manufacturing of human and veterinary medicines. Based on this data, ex-factory sales of CANIFARMA members showed an insignificant increase between 2007 and 2013: an average annual rate of 0.006%, from MXN 165 009 million in 2007 to MXN 165 072 million in 2013 (CANIFARMA, 2015).

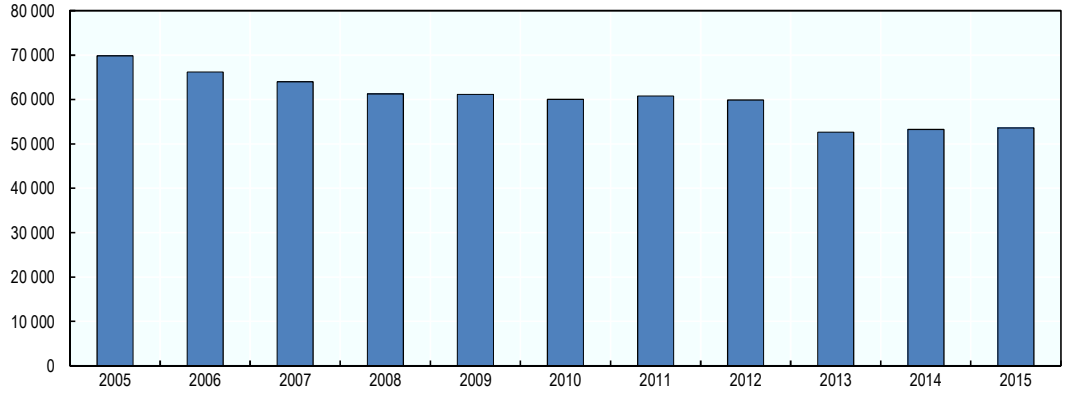
CANIFARMA members' ex-factory sales of medicines for human use to the private sector during the period 2007-2013 oscillated between 62% and 71%, while the share of sales to the public sector oscillated between 24% and 30%, and the share of exports remained below 10%.

Figure 2.5. **Ex-factory sales of medicines for human use (2015 MXN, millions), destination shares (%) and annual growth (%), 2007-2013**



Source: CANIFARMA (2015), *Compendio Estadístico de la Industria Farmacéutica en México (2007-2013)*

Figure 2.6. **Number of employees in medicine manufacturing**



Source: INEGI, Banco de Información Económica, Sistema de Cuentas Nacionales de México

Number of employees

From 2005 to 2015, the number of employees active in medicine manufacturing decreased continuously, at an average annual rate of 2.6%, from 69 846 employees in 2005 to 53 535 in 2015.

2.1.3.2 Wholesale

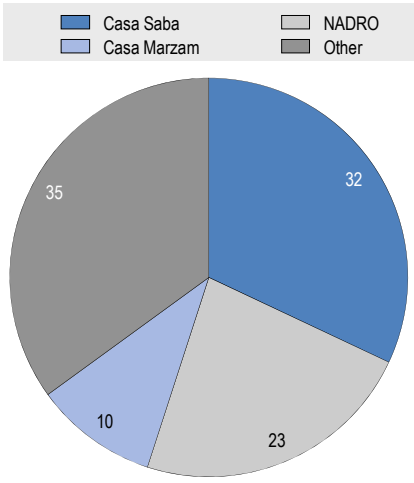
Most laboratories neither distribute nor trade their products directly (not even to pharmacy chains), but rather sell them through wholesale distributors. Those wholesalers manage, store, transport and deliver final products to pharmacies and hospitals. Wholesalers sometimes provide additional services, such as granting credits and handling payment processes.

Market participants

In 2012, four firms accounted for 58% of medicine distribution to the private sector: Casa Saba[19] Nacional de Drogas (NADRO), Casa Marzam and Fármacos Nacionales. Two medium-sized players, Proveedoras de Medicamentos and Almacenes de Drogas, and 33 smaller firms specialised in regional distribution shared the remaining market (Fundación Mexicana para la Salud, 2013).

In 2013, the *Mexican Health Review* (2015) found that the three biggest competitors – Casa Saba, NADRO and Casa Marzam – controlled as much as 65% of the total distribution market (Casa Saba: 32%; NADRO: 23%; Casa Marzam: 10%).

Figure 2.7. **Market share of wholesalers, 2013 (%)**

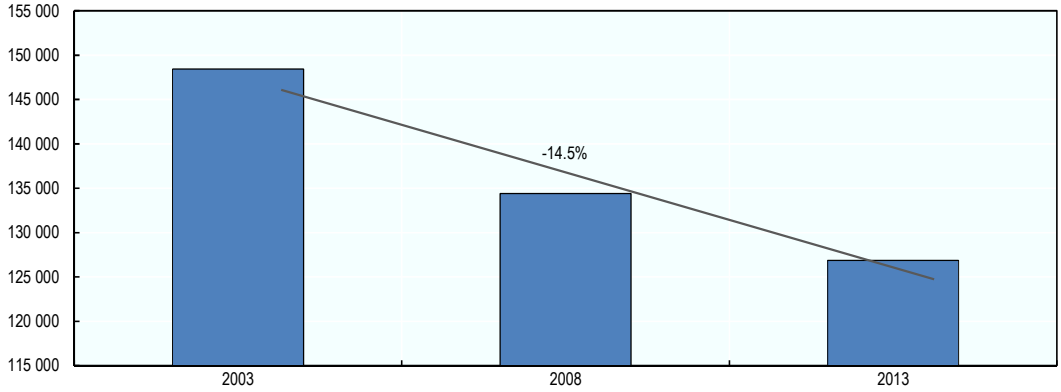


Source: Mexico Health Review (2015)

Turnover by value and number of employees

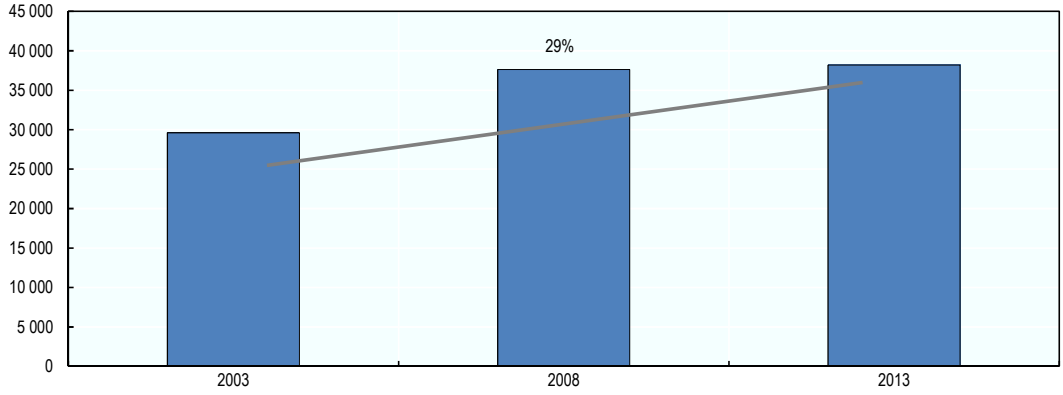
According to INEGI census data, the aggregated turnover of all wholesalers constantly decreased between 2003 and 2013, while turnover decreased in real terms by 14.5%. Yet somewhat surprisingly, the number of employees increased by 29% during the same period. As of 2013, there were 38 198 employees.[20]

Figure 2.8. **Turnover of medicine wholesale distribution (2015 MXN, millions)**



Source: INEGI 2004, 2009 and 2014 Censuses, Sistema Automatizado de Información Censal

Figure 2.9. **Number of employees in medicine wholesale distribution**



Source: INEGI 2004, 2009 and 2014 Censuses, Sistema Automatizado de Información Censal

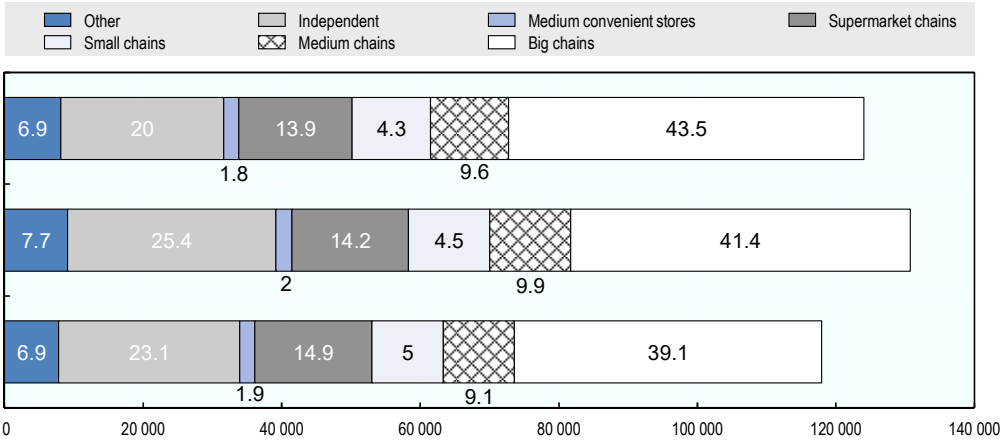
2.1.3.3. Retail

Market participants

As of 22 March 2017, there were 56 699 active pharmacies in the Mexican retail market.[21] There were also 20 131 establishments that did not sell allopathic medicines, but rather homeopathic medicines, herbal medicines and/or food supplements.

Pharmacies can be independent, belong to chains, to supermarkets or to the government. The share of chain pharmacies in total pharmacy sales steadily increased between 2012 and 2014: from 53.2% to 57.4%.

Figure 2.10. **Sales in the retail sector (nominal MXN, millions) and share of pharmacy formats (%)**



Source: Mexico Health Review (2015)

According to press sources,[22] Farmacias del Ahorro, Farmacias Guadalajara and Farmacias Benavides were the three largest pharmacy chains in 2015.

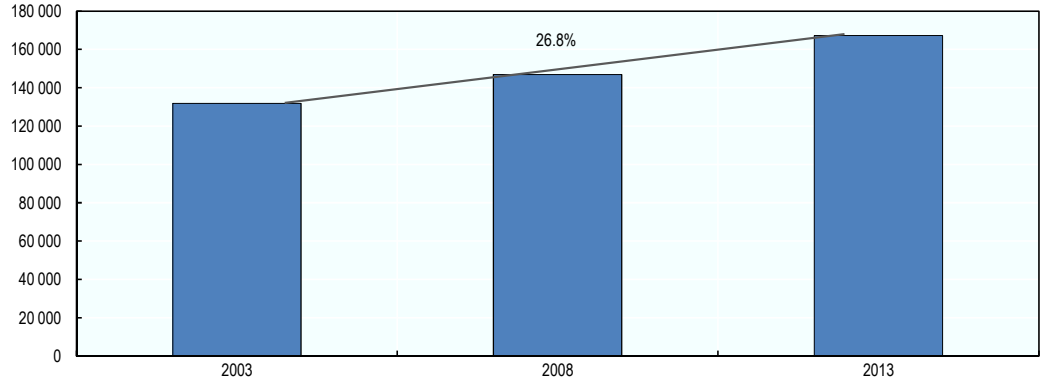
In February 2015, just over half of pharmacies in Mexico (53.5%) had an adjacent doctor's office (Consultorio Adyacente a Farmacia or CAF), according to COFEPRIS.[23]

CAF play an important role in Mexico's health system, assuring fast and affordable medical access to a significant part of the population. Indeed, in 2013, CAF provided over 250 000 daily medical visits, while IMSS provided nearly 290 000.[24] However, as virtually all CAF belong to pharmacies, doctors are not always completely free in their prescription practice as they can receive financial incentives from pharmacies based on their prescription practices (e.g. bonuses for high volumes of medicines prescribed).

Turnover, number of establishments and number of employees

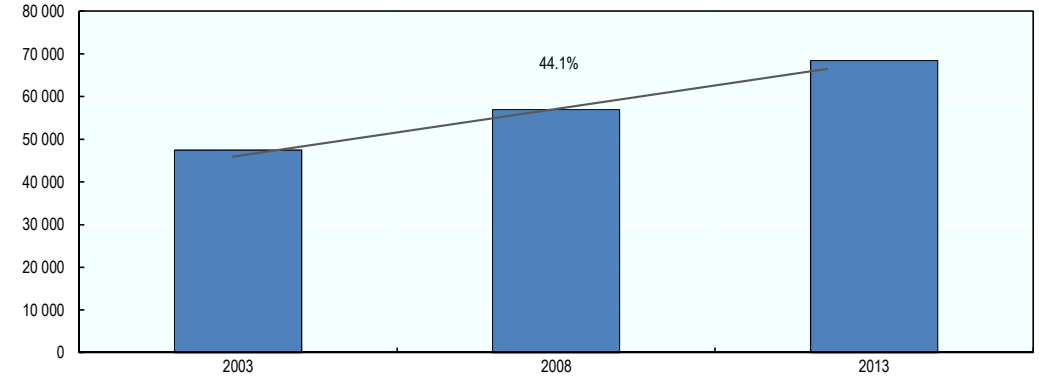
Over the past decade, in contrast to wholesale-distribution turnover, the retail sector in pharmaceuticals has been growing significantly. According to INEGI census data, aggregated turnover, measured in real terms, increased by 26.8% between 2003 and 2013, an implied average annual growth rate of 2.4%. In addition, between 2003 and 2013, the number of establishments and employees increased by 64.2% and 44.1%, respectively (to 68 395 establishments and 245 522 employees in 2013).[25]

Figure 2.11. **Turnover of pharmaceutical retail (2015 MXN, millions)**



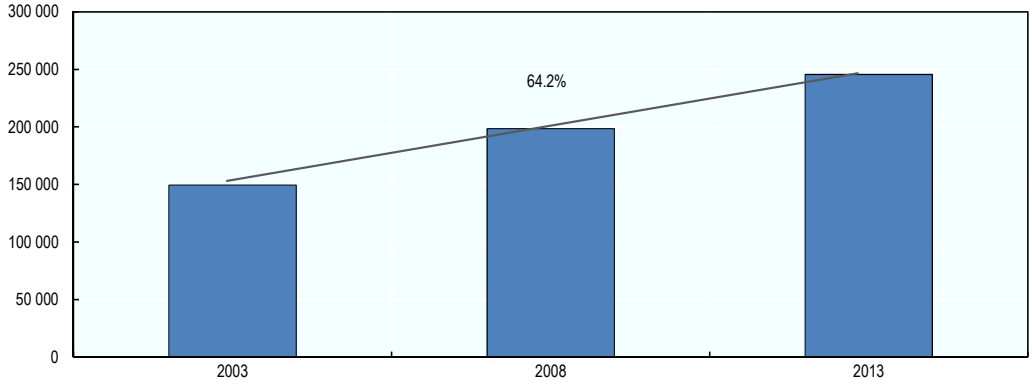
Source: INEGI 2004, 2009 and 2014 Censuses, Sistema Automatizado de Información Censal

Figure 2.12. **Number of establishments in pharmaceutical retail**



Source: INEGI 2004, 2009 and 2014 Censuses, Sistema Automatizado de Información Censal

Figure 2.13. **Number of employees in pharmaceutical retail**



Source: INEGI, 2004, 2009 and 2014 Censuses, Sistema Automatizado de Información Censal

2.1.3.4. Demand side

Main health institutions

The main institutions providing health insurance in Mexico and so purchasing pharmaceuticals are the following.[26]

- **IMSS.** IMSS is in charge of the administration of social insurance, the basic instrument of social security in Mexico. IMSS provides benefits under its compulsory and voluntary regimes: in the compulsory regime, employers are mandated to register their employees. In turn, the voluntary regime is meant for workers who are no longer employed, but who wish to continue contributing to IMSS in order to benefit from health coverage and pensions (e.g. the self-employed, communal landholders, employers, domestic workers or public-sector workers at the federal, state or municipal levels, who are excluded or not covered by a social-security regime). In 2015, IMSS covered approximately 59.1% of the Mexican population (IMSS, 2015).
- **ISSSTE.** ISSSTE provides health insurance to officials/employees working for the federal and state governments. ISSSTE covers approximately 10.6% of the Mexican population.
- **Other public insurance programmes.** PEMEX, the Ministry of Navy, and the Ministry of National Defence each has its own special public system, providing health coverage to employees. The three institutions jointly cover 1.6% of the Mexican population.
- **Seguro Popular (SP).** Created in 2004, SP is a system of voluntary public insurance established by the Mexican government in an effort to expand health-care coverage. By 2014, SP had gradually expanded to cover more than 57 million people or 47.6% of the Mexican population.

Private insurance

Approximately 8% of the Mexican population is covered by private health insurance.[27]

According to the National Council for the Evaluation of Social Development Policy (Consejo Nacional de Evaluación de la Política de Desarrollo Social, CONEVAL), 18.2% of the Mexican population had no access to medical coverage in 2014, making all their medicines out-of-pocket expenses (CONEVAL, 2015).

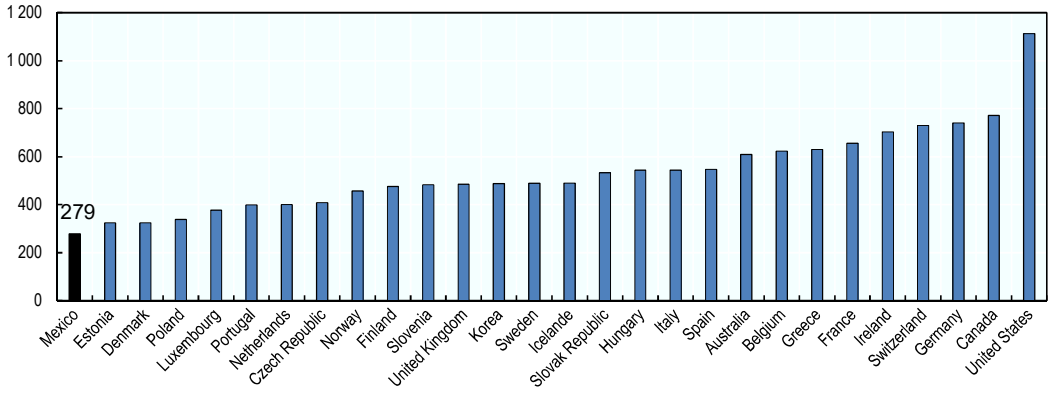
Public institutions that provide health insurance in Mexico have their own networks of hospitals and medical units, including physicians and required health suppliers, to guarantee medical care to their affiliates.

These public health institutions mostly use public-tender procedures when purchasing health supplies. Since 2012, IMSS has been bundling its purchases together with ISSSTE and, gradually, other public institutions.[28] In December 2016, for example, IMSS and ISSSTE consolidated their purchases with PEMEX, the Ministry of Navy and the Ministry of National Defence, and other 18 state-government institutions and 17 institutions from the Ministry of Health, for the biggest public-sector order in Mexican history, worth MXN 41 861 million.[29]

Medical spending in Mexico

In 2014, per-capita pharmaceutical spending in Mexico was USD 279,[30] one of the lowest among a selection of 28 OECD countries.

Figure 2.14. **Pharmaceutical spending per capita (USD) across OECD countries, 2014***

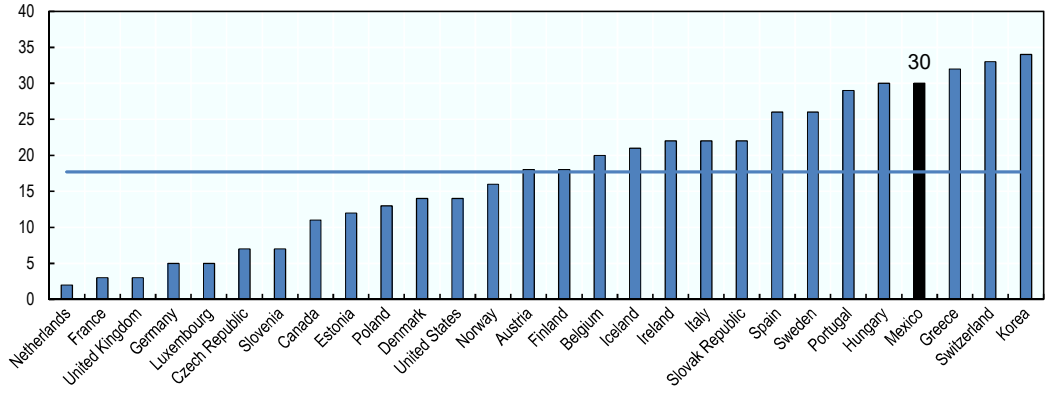


* The value for the Netherlands is underestimated as it excludes compulsory co-payments by patients to health insurers; if these were taken into account, the share would double.

Source: OECD (2017), "Pharmaceutical spending (US dollars/per capita)"

However, as shown in Figure 2.15, out-of-pocket medical spending in Mexico as a share of household consumption was among the highest among the OECD 28 in 2015. While the average out-of-pocket spending share among the OECD 28 was 17.7%, Mexican spending accounted for 30% of household consumption. In Mexico, the OECD has found that out-of-pocket spending "has not fallen significantly across the past decade, despite efforts to achieve universal health coverage through the SP reform. Reasons for sustained, high levels of spending out-of-pocket are unclear. Part of the reason may be dissatisfaction with the quality or accessibility of services provided by institutions to which individuals are affiliated, leading them to seek care from private health providers" (OECD, 2016d).

Figure 2.15. **Share of out-of-pocket medical expenditure in household consumption (%) across OECD countries, 2015***

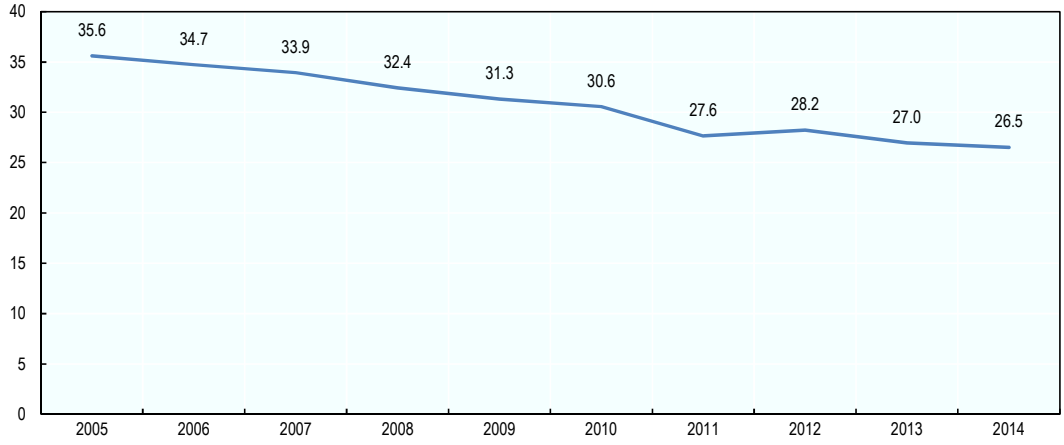


* The ranking for the Netherlands is overrated as it excludes compulsory co-payments to health insurers.

Source: OECD (2015), *Health at a Glance 2015*

The share of pharmaceutical spending as a part of health spending steadily decreased from 35.6% in 2005 to 26.5% in 2014. This is probably due to increasing use of generics.

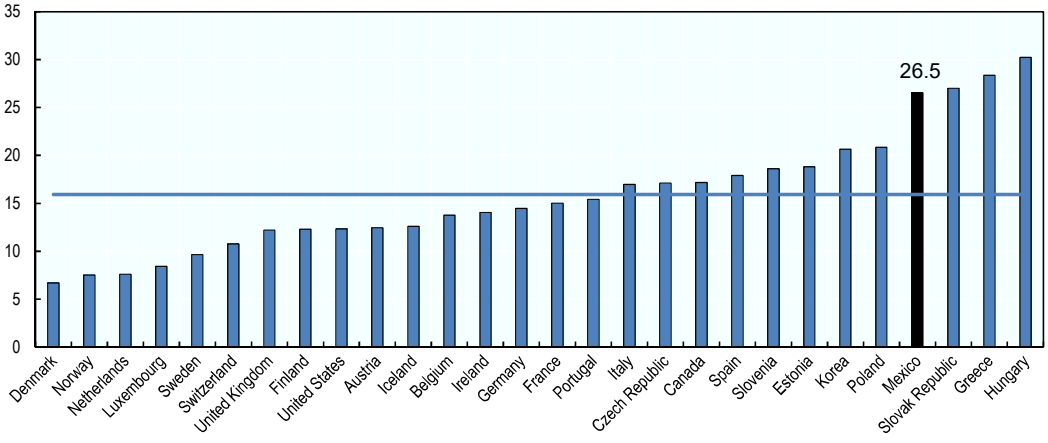
Figure 2.16. **Pharmaceutical spending as a percentage of health spending (%), 2005-2014**



Source: OECD (2017), "Pharmaceutical spending (% of health spending)"

In spite of this downward trend, pharmaceutical spending as part of health spending in Mexico is still relatively high when compared to other countries. In 2014, among the OECD 28, Mexico ranked 25th with 26.5%, above the average of 15.9%.

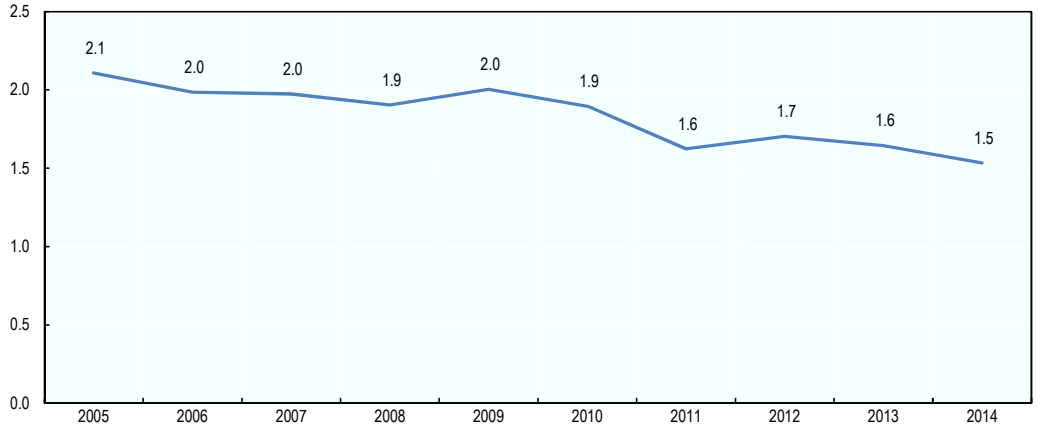
Figure 2.17. **Pharmaceutical spending as a percentage of health spending (%) across OECD countries, 2014**



Source: OECD (2017), "Pharmaceutical spending (% of health spending)"

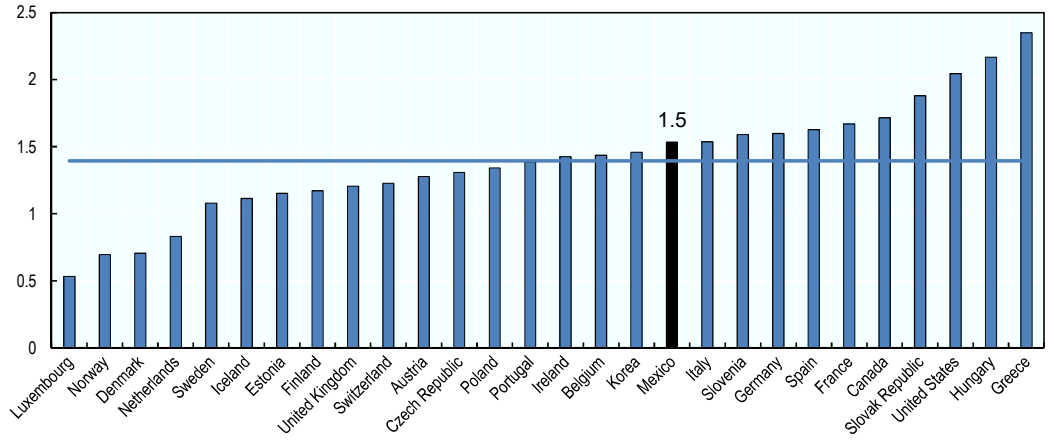
As depicted in Figure 2.18, Mexico's share of pharmaceutical spending as percentage of GDP decreased from 2.1% in 2005 to 1.5% in 2014. This percentage was close to the 1.4% average of the OECD 28.

Figure 2.18. **Pharmaceutical spending as a percentage of GDP (%), 2005-2014**



Source: OECD (2017), "Pharmaceutical spending (% of GDP)"

Figure 2.19. **Pharmaceutical spending as a percentage of GDP (%) across OECD countries, 2014**

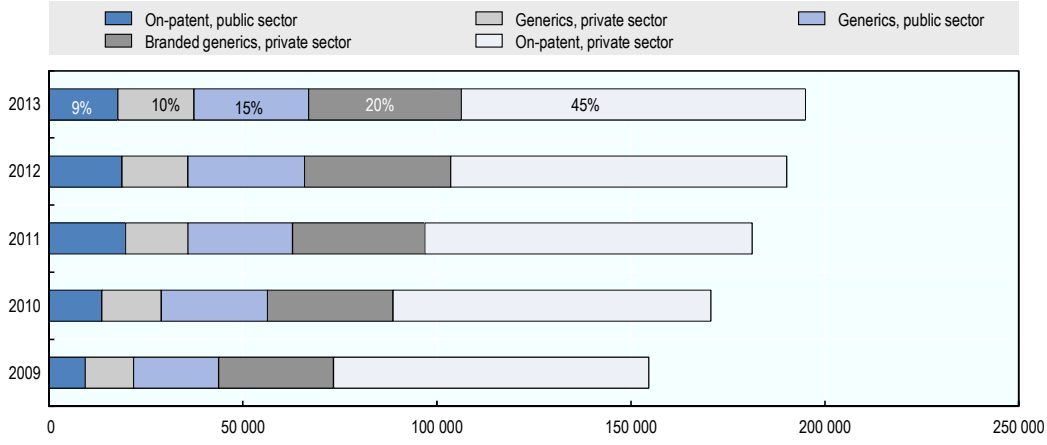


Source: OECD (2017), "Pharmaceutical spending (% of GDP)"

2.1.4. Sales of generics and patented medicines by value and volume

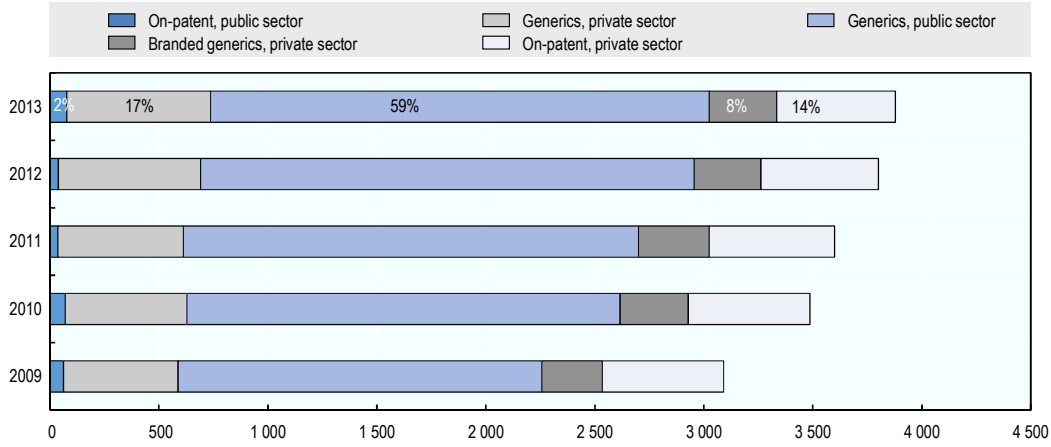
Figures 2.20 and 2.21 show the Mexican medicine market broken down by type, in value and volume, respectively. In 2013, generics accounted for the largest part of the market in units (84%), while on-patent medicines represented the biggest part of the market by value (54%).[31]

Figure 2.20.**Total medicine market by value (MXN, millions), by type, 2009-2013**



Source: PharmaBoardroom in collaboration with CANIFARMA (June 2015), *Healthcare Life Sciences & Review*, with data from IMS Health

Figure 2.21. **Total medicine market in units (millions), by type, 2009-2013**

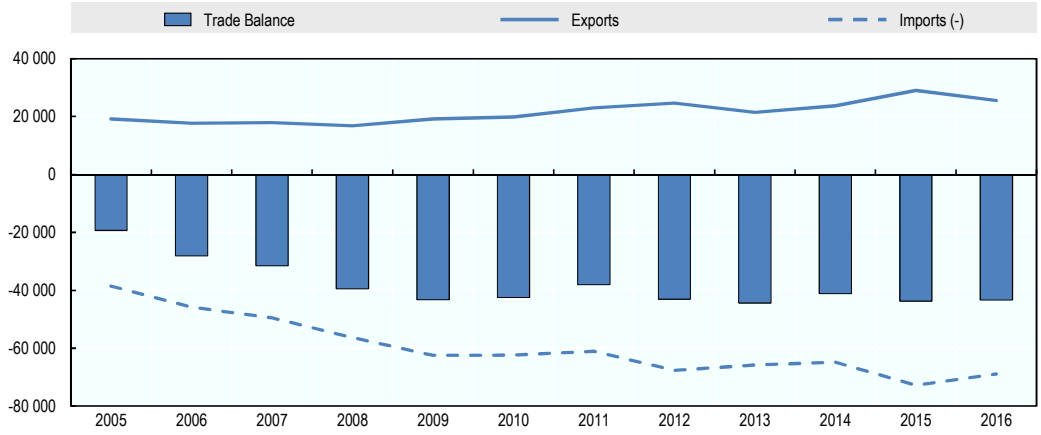


Source: PharmaBoardroom in collaboration with CANIFARMA (June 2015), *Healthcare Life Sciences & Review*, with data from IMS Health

2.1.5. International trade

Between 2006 and 2016, the value of imports of all medicines – including both on- and off-patent – grew, in real terms, at an average annual rate of 4.2%, while the value of exports increased by 3.7%. Over the same time period, and on a month-by-month basis, imports were constantly higher than exports, however; on average, 2.8 times exports. This resulted in a constant negative trade balance for medicines in Mexico.

Figure 2.22. **Imports and exports of medicines (2015 MXN, millions), 2006-2016***



* Import and export values were obtained from INEGI's External Sector Statistics, including values in the chapter "Pharmaceutical products", which is part of section VI, "Products from the chemical industry or related industries", minus the value of the subchapter "Wadding, gauze, bandages". The values are monthly thousands of USD from January 2006 until December 2016. The monthly FIX exchange rate for MXN to USD from Banxico was used. After obtaining the value in thousands of MXN, each monthly value was deflated using INEGI's Producer Price Index of and converted to millions. Finally, an annual estimation was obtained considering the sum of the monthly values.

Source: INEGI, Banco de Información Económica, Sector Externo

According to PROMÉXICO, medicines imported into Mexico in 2014 came from the United States (21%), Germany (18%) and France (11%);[32] the main final export destinations for medicines in 2015 were Switzerland (23.1%), the United States (22.4%) and Panama (7.8%).[33]

Table 2.3. **Country of origin of imported medicines (2014)**

Country	Value (USD, millions)	Market share
United States	1 045	21%
Germany	901	18%
France	559	11%
Puerto Rico	423	9%
Switzerland	303	6%
Italy	215	4%
Canada	189	4%
Ireland	118	2%
Belgium	115	2%
Spain	112	2%
Other	958	19%

Source: PROMÉXICO, Unidad de Inteligencia de Negocios (2015), *Industria Farmacéutica y Oportunidades de Negocio en México*

Table 2.4. **Country of destinations of exported medicines (2015)**

Country	Value (USD, millions)	Market share
Switzerland	452	23%
United States	438	22%
Panama	153	8%
Venezuela	128	7%
Colombia	109	6%
Ecuador	75	4%
Guatemala	75	4%
Brazil	72	4%
Canada	64	3%
France	53	3%
Other	339	17%

Source: PROMÉXICO, Unidad de Inteligencia de Negocios (n.d.), *Diagnóstico Sectorial Farmacéutico*

Before 5 August 2008, companies wishing to import medicines into Mexico were required to own infrastructure in the country. Since then, foreign medicines producers can import their products into Mexico without owning infrastructure as long as they hold a licence to produce medicines in their countries of origin.

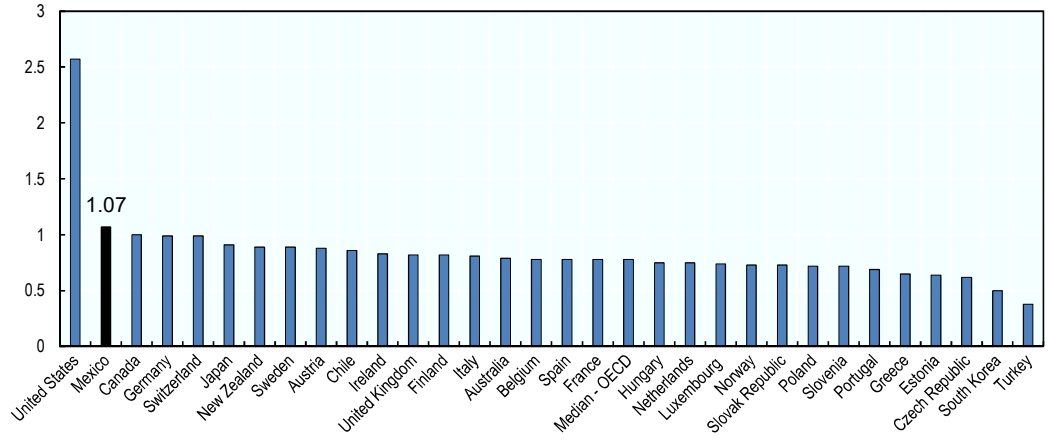
2.1.6. International price comparisons

There are no recent studies of comprehensive price comparisons between Mexico and other countries. However, some representative studies do exist, including one from 2015 that uses a sample of patented medicine prices in OECD countries, which is then compared to Canadian prices.

2.1.6.1. OECD prices 2015

In its *Annual Report 2015*, Canadian Patented Medicine Prices Review Board (PMPRB) compared prices for medicines in Canada with other OECD countries. In 2015, according to the price comparison shown in Figure 2.23, Mexican prices for patented medicines were higher than all other OECD countries except the United States.

Figure 2.23. **Average foreign-to-Canadian price ratios, patented medicines, OECD countries, 2015***



* Canadian and international prices reported in health-data consultancy IMS's MIDAS database were used. MIDAS summarised data obtained from IMS's audits of pharmaceutical purchases. The index of the average foreign-to-Canadian price ratios were constructed using Canadian sales-weighted arithmetic averages of the corresponding foreign-to-Canadian price ratios for individual medicines.

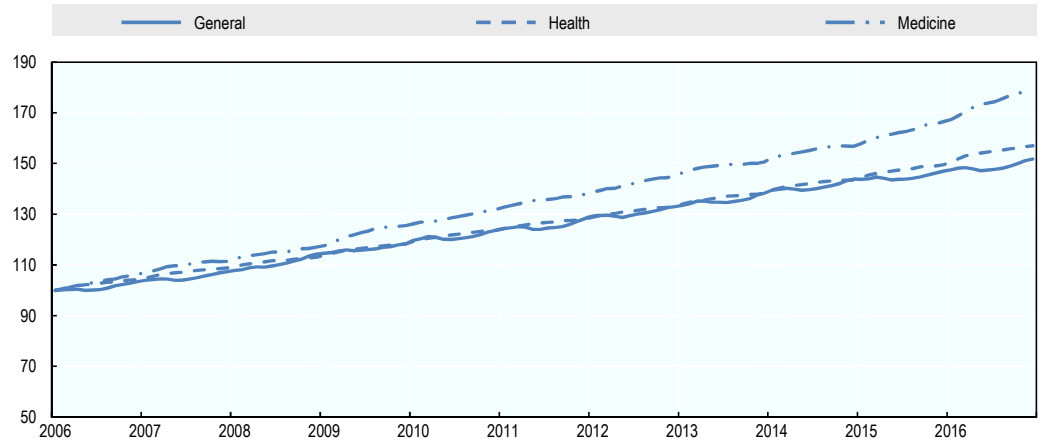
Source: PMPRB (2015), *Annual Report 2015*

2.1.6.2. Medicine prices compared to other consumer prices

Since 2006, medicine prices in Mexico have been rising more quickly than both health-sector prices and general prices, as measured by the Consumer Price Index.[34] Over the past six years (December 2011-December 2016), medicine prices increased at an average annual rate of 5.4%, resulting in a total rise of 30% over the period. Over the same period, general prices only increased by 18%, with average annual growth of 3.4%.

As shown in Figure 2.24, health-care price levels and general prices followed a very similar trajectory between December 2006 and December 2016 (on average, health price levels were 1.3% higher than general prices). Medicine prices, however, have increased more than general prices and shown a greater and growing gap: on average 8.7% for the same period and 11.7% for the past five years.

Figure 2.24. **Consumer Price Indexes, 2006-2016**

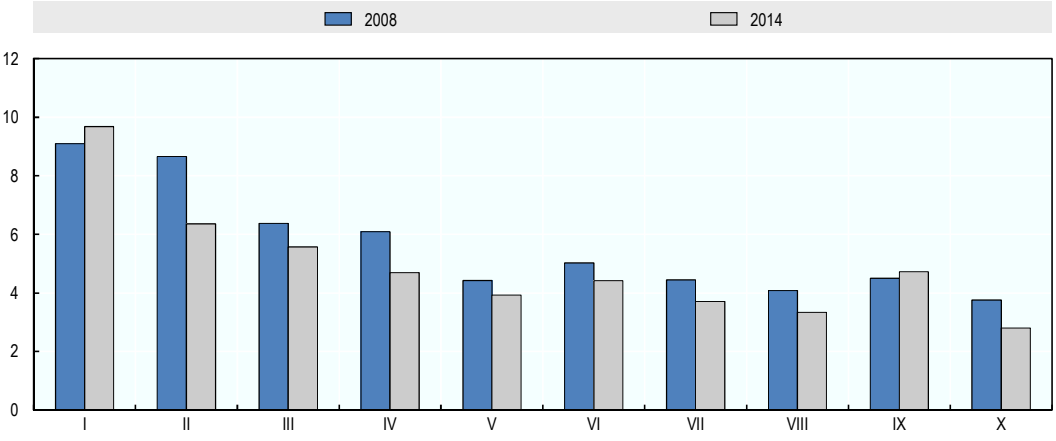


Source: INEGI, Índices de Precios al Consumidor

2.1.6.3. Pharmaceutical spending as share of household spending

Recently, average per-household, out-of-pocket spending on pharmaceuticals (medicines with prescription, OTC and healing material) has decreased. In 2008, the average Mexican household spent MXN 1 143 on pharmaceuticals, which represented 5.2% of its overall expenses. In 2014, it spent MXN 1 193, or 4.5% of its total expenses. Poorer households, however, continue to assign a higher share of their spending to medicines. Indeed, the poorest 10% of households (decile I) spent MXN 592 on average in 2008 (9.1% of their total spending) and MXN 759 in 2014 (9.7%), while the richest households (decile X) spent MXN 2 271 on average in 2008 (3.8% of their total spending) and MXN 2 286 in 2014 (2.8%).[35]

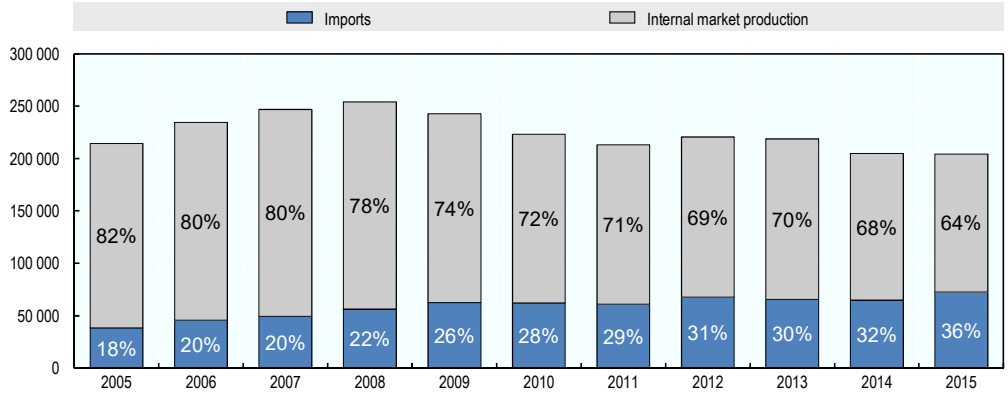
Figure 2.25. **Household expenses on pharmaceuticals (%) per income deciles, 2008 and 2014**



Source: INEGI, Encuesta Nacional de Ingresos y Gastos de los Hogares

With the exception of 2013, imports of medicines steadily increased as a percentage of apparent domestic consumption between 2005 and 2015:[36] in 2005, it represented 18% of apparent domestic consumption, by 2015, the figure was 36% (OECD, 2015).[37]

Figure 2.26. **Domestic consumption of medicines (2015 MXN, millions), 2005-2015**



Source: INEGI, Sistema de Cuentas Nacionales de México and INEGI, Sector Externo

2.1.7. Relevant authorities and associations

2.1.7.1. Authorities

In Mexico, the main health authorities dealing with medicines are the President of Mexico, the Ministry of Health and the state governments, the Federal Commission for the Protection against Sanitary Risk (Comisión Federal para la Protección contra Riesgos Sanitarios, COFEPRIS), and the General Health Council (Consejo de Salubridad General).

- **President of Mexico.** The President of Mexico appoints the Minister of Health, as well as the members of the General Health Council, and approves the regulation of the organisation and functioning of the General Health Council. He is also responsible for designating the Federal Commissioner in charge of COFEPRIS.
- **Ministry of Health.** The Ministry of Health implements the President's national health policy by:
  - coordinating the National Health System (Sistema Nacional de Salud), which comprises public administration entities, both federal and local, and the natural and legal persons from social and private sectors providing health services to the Mexican population
  - laying down Mexican Official Standards (Normas Oficiales Mexicanas, NOMs) related to the provision of health services
  - verifying compliance with NOMs, the General Health Law and any other applicable legal provision in health matters
  - evaluating the provision of health services.
- **Federal Commission for the Protection against Sanitary Risk (COFEPRIS).** COFEPRIS protects the Mexican population against health risks by issuing or revoking sanitary authorisations (mainly licences, permits and registries) concerning establishments that provide health services, manufacture and process medicines, health inputs and food supplements. Further tasks for COFEPRIS include:

- controlling and monitoring health facilities
- prevention and control of environmental effects harmful to human health
- regulation, control and promotion of occupational health and basic sanitation
- sanitary control of products and services, imports and exports
- control of advertising related to health.

COFEPRIS, which is also involved in drafting NOMs, is overseen by the Ministry of Health.

- **General Health Council (Consejo de Salubridad General).** The General Health Council is in charge of issuing opinions about scientific research projects and studies, as well as those related to human-resources training for the health sector. It is composed of a president (the Minister of Health), a secretary and 13 other members.[38] The Council elaborates, updates and distributes the Basic Formulary of Health Inputs for the first level of medical care, as well as the Input Catalogue for the second and third levels.

- **Federal Attorney's Office of Consumer (Procuraduría Federal del Consumidor, PROFECO).** PROFECO, a body of the Ministry of Economy, is in charge of consumer-protection policy. Its powers are regulated by the Federal Law on Consumer Protection. In particular, PROFECO manages a database comparing selected prices of medicines in various cities and stores across Mexico as part of the "Who's Who in Prices" (Quién es Quién en los Precios) programme.[39] PROFECO occasionally publishes special reports for particular products, and has done so for medicines. PROFECO also resolves complaints related to service contracting and product purchasing, and produces and publishes reports on the quality and features of different products and services in order to guide and protect consumers. In these reports, it makes specific mention of brands; companies are not, however, permitted to quote PROFECO's opinions of brands.

- **Committee on New Molecules (Comité de Moléculas Nuevas, CMN).** The CMN is a consultation body that issues opinions on the safety, quality and effectiveness of medicines that require an evaluation. The Ministry of Health demands CMN's opinion when placing medicines featuring new molecules on the sanitary registry. It is composed of a president (COFEPRIS' Sanitary Authorisation Commissioner), a vice president (COFEPRIS' Executive Director of Product Authorisation and Establishments), a technical secretary (Director of the National Pharmacovigilance Centre) and representatives of Mexican academic associations.

2.1.7.2. Trade associations

- **CANIFARMA** is the Mexican pharmaceutical industry's main trade association. Created in 1946, it currently has 186 members, including companies that manufacture medicines (patented and generics) for human and veterinary use, as well as companies that produce medical devices.[40]

- **National Association of Medicine Manufacturers (Asociación Nacional de Fabricantes de Medicamentos, ANAFAM)** is an association of 26 national pharmaceutical companies. According to its website, ANAFAM members

produce 60% of all medicines sold to the public sector and 17% of all medicines sold to the private sector in Mexico.[41] One of ANAFAM's objectives is to promote generics.

- **Mexican Association Industries for Research (Asociación Mexicana de Industrias de Investigación Farmacéutica, AMIIF)** represents more than 40 national and international pharmaceutical and biotech companies operating in Mexico. Its mission includes promoting pharmaceutical research.
- **National Association of Medicine Distributors (Asociación Nacional de Distribuidores de Medicinas, ANADIM)** is an industry association representing 19 Mexican companies active in the regional distribution and retail of medicines, perfumes and personal-care products. According to its website, in 2015, ANADIM accounted for 54.7% of national pharmaceutical retail market (by value).[42] Its members operate 7 550 points of sale.[43]
- Mexican Association of Interchangeable Generics Manufacturers (Asociación Mexicana de Fabricantes de Medicamentos Genéricos Intercambiables, AMEGI) is a representative body for generic producers composed of six members. According to its website, AMEGI's members produce 80% of the units consumed by the health sector.[44]
- **National Union of Pharmacy Entrepreneurs (Unión Nacional de Empresarios de Farmacias, UNEFARM)** is a Mexican trade association comprising 25 groups of independent pharmacies. According to its website, UNEFARM organises joint purchases for its members.[45]
- **National Association of Pharmacies in Mexico (Asociación Nacional de Farmacias de México, ANAFARMEX)** is a national trade association of pharmacies. According to its website, ANAFARMEX represents more pharmacies than any other representative body. It provides training to pharmacy operators on medicine dispensing.[46]

2.2. Overview of the legislation

The pharmaceutical sector is heavily regulated: "All aspects of the life cycle of new drugs are regulated, from patent application, to market approval, commercial exploitation, patent expiration and competition with generics" (OECD, 2000: 7). All relevant actors in the pharmaceutical sector (i.e. manufacturers, wholesalers, retailers, and prescribing doctors) are also subject to legal control.

The main objectives of regulation are preserving incentives for research and development and the flow of new innovative drugs, while assuring the efficacy of pharmaceutical products, their quality, as well as their safety (OECD, 2000: 7).

From both an ethical and economic perspective, pharmaceutical products have special characteristics. They tend to be considered as "merit goods" meaning that patients should be able to acquire them irrespective of their ability to pay for them. This feature usually leads governments to provide public-health services that tend to include the supply of medicines and, often, the regulation of prices.

In addition, pharmaceutical products are so-called "credence goods" (OECD, 2014: 4). This implies that their consumption is subject to specific knowledge about when and how they should be used. As patients usually lack the medical knowledge to assess the

medical advice they receive, they rely entirely on a doctor's good judgement about which particular medicines should be part of their medical treatment. The asymmetries of information between the doctor and the patient usually require some type of protection to ensure doctors' prescribing practices respond to patients' best interests and not to arrangements doctors may have with pharmaceutical companies.[47] In Mexico, this is currently regulated by a code of conduct of one of the main pharmaceutical associations; this code contains a legal lacuna that the OECD recommends resolving.

The mapping of Mexican legislation for the pharmaceutical sector included 117 legal provisions, including laws, regulations, ministerial decrees, as well as guidelines and agreements from official authorities. Almost 40% of the regulations address the production of medicines; the remaining 60% refer almost evenly to the wholesale of pharmaceutical products, retail, and horizontal legislation. Ultimately, we found 100 restrictions, for which we have issued 50 recommendations.

Pharmaceutical legislation in Mexico is extensive. Two main pieces of legislation act as general frameworks: the General Health Law (Ley General de Salud) and the Regulation on Health Inputs (Reglamento de Insumos para la Salud).

The General Health Law was first enacted in February 1984; it has been constantly amended since then.[48] It regulates the right-to-health protection granted by the Mexican Constitution, providing a general guideline on most health topics, including marketing authorisations, import of medicines, advertising of pharmaceutical products, the transport of medicines, qualifications necessary to act as a health professional, health education, access to health, and health promotion.

The Regulation on Health Inputs came into force on 4 February 1998 and was last modified in 2014. It regulates the sanitary control of medicinal inputs, herbal medicines, as well as the control of all medical establishments, activities, and services related to them. This regulation is an important complement to the General Health Law, clarifying many topics discussed in this report such as the prescription of medicines, marketing authorisations, the import and export of medicines, advertising of pharmaceutical products, and labelling of medicines.

The main restrictions identified are presented in detail in the following sections. It is the OECD's belief that the implementation of its recommendations would have a significant effect on the Mexican economy. The OECD's best estimates indicate benefits amounting to at least MXN 10 177.1 million and might go up to MXN 43 813.8 million, which derive from recommendations that would affect the incentives to doctors; the ability of consumers to switch to generics when doctors prescribe branded medicines; and the direct sales from pharmaceutical producers to retailers.

2.3. Restrictions to competition in the pharmaceutical sector

2.3.1. Incentivisation of doctors

Patients seek doctors' assistance because they assume that doctors are in the best position to provide a diagnosis of their health and suggest the correct treatment. Medical treatment often involves the prescription of medicines. This prescription practice requires specific knowledge to determine when and how a medicine should be used. Given the asymmetry of information between the prescribing doctor and the patient, medicines are known as "credence goods", i.e. a good whose utility impact is difficult or impossible for

the consumer to ascertain and where the patient has to believe the doctor (OECD, 2014: 4).

This asymmetry may lead to problems if doctors benefit from the sale of specific medicines. Conflicts of interest can especially arise when doctors are allowed to dispense pharmaceutical products themselves (OECD, 2014: 7) or when they receive pecuniary advantages from pharmaceutical companies, such as invitations for out-of-town conferences, the free provision of medical equipment that they would otherwise need to purchase, or speaker fees. These conflicts of interest may lead to the over-prescription of drugs. If doctors somehow benefit from the number of units sold, they may have incentives to prescribe more medicines than necessary.

Also, doctors may not prescribe the most cost-effective medicine, but the one that provides them with a pecuniary benefit, e.g. by prescribing a patented drug even when there are generics in the market. When there is only one patented medicine in the market to cure a certain disease, doctors have no alternative but to prescribe the patented drug and patients have no alternative but to purchasing it. However, after patents expire, patients may usually benefit from generics entering the market at a lower price than the innovative product. Studies have shown that generics generally work as well as innovative drugs.[49] Nonetheless, despite their similar effectiveness, doctors may prescribe the more expensive alternative if they obtain an extra benefit from prescribing the innovative product.

In this report, all forms of pecuniary benefits given by pharmaceutical companies to doctors, and which might motivate doctors to prescribe a certain drug are referred to as the "incentivisation of doctors". In this area, the OECD makes two recommendations for filling the legal lacuna about the granting of financial advantages, as well as the monitoring of doctors' prescription practice.

2.3.1.1. Legal lacuna concerning pecuniary advantages to incentivise doctors

Description of the relevant obstacle. Mexico currently has no law regulating which benefits pharmaceutical companies can provide to doctors, such as conference participations or speaker engagements. There is, however, an ethics code issued by CETIFARMA, a subsidiary of pharmaceuticals trade association CANIFARMA, which regulates and monitors the ethics code that addresses pecuniary incentives. This ethics code, however, only applies to CANIFARMA members. According to CETIFARMA, providing financial incentives of significant value to doctors is forbidden. Infringement of the code is subject to admonition, pecuniary penalties (though no amounts are detailed), as well as temporary or definitive suspension of the rights as a CANIFARMA affiliate.

Harm to competition. Despite the existence of CETIFARMA's Ethics Code, according to market participants, providing pecuniary advantages to doctors is not a rare practice among pharmaceutical companies. Not all pharmaceutical companies are members of CANIFARMA (87%, according to its own figures) and so bound by its code of conduct. A lack of binding governmental regulation in this field may hinder competition among similar products. Doctors might be provided by some pharmaceutical companies with benefits that lead them to prefer one product over one that they might regard as best suited to, or most economical for, the patient. Pharmaceutical companies that comply with the CETIFARMA code of conduct or that do not supply any benefits to doctors for other reasons might be discriminated against. The problem might be aggravated by the fact that pharmaceutical companies are, at least theoretically, able to

gather data concerning the prescribing practice of individual doctors – which allows them to target and monitor these doctors.

Policymaker's objective – International comparison. The risk described above has led to various regulatory responses. Two main models have emerged:

1. The European model bans pecuniary advantages, as a general rule.[50] According to European Union Law, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. Also, hospitality at sales-promotion events shall always be strictly limited to the events' main purpose and must not be extended to persons other than health-care professionals.[51]
2. The US model is mainly based on self-regulation and requires pharmaceutical companies to disclose financial agreements they may have with doctors. Nonetheless, the US model also bans, as a general rule, gifts of significant value.[52]

Box 2.1. **Prescribing patterns and pecuniary advantages***

In 2016, ProPublica, a US-based "independent non-profit newsroom that produces investigative journalism", carried out an analysis examining if there existed a relationship between industry payments and brand-name prescribing by doctors in the United States. The study found that physicians in five common medical specialties who accepted at least one industry payment were more likely to prescribe high rates of brand-name drugs than physicians who did not receive any payments. ProPublica also compared average prescribing rates among physicians based on whether they received payments or not; those who received large USD amounts of payments and those who received smaller amounts; and those who received certain types of payments (e.g. meals, speaking) and those who did not.

In all cases, the group receiving larger payments had, on average, a higher brand-name prescribing rate. Also, the type of payment made a difference: those who received meals alone from companies had a higher rate of brand-name prescribing than physicians who received no payments, and those who received speaking fees showed a higher rate of prescribing branded drugs than those who received other types of payments.

Similarly, Toshiaki Iizuka, in a 2007 study carried out in Japan, found that doctors' prescribing patterns were affected by the margin they can earn, discovering over-prescription as well as the prescription of sub-optimal drugs. Nonetheless, there were differences among insured and non-insured patients. Doctors tended to overprescribe more for the former group of patients than the latter.

* Jones, Ryan Grochowski & Charles Ornstein (2016), "Matching Industry Payments to Medicare Prescribing Patterns: An Analysis", https://static.propublica.org/projects/d4d/20160317-matching-industry-payments.pdf?22; Iizuka, Toshiaki (2007), "Experts' Agency Problems: Evidence from the Prescription Drug Market in Japan", RAND Journal of Economics 38:3, pp. 844-862, www.jstor.org/stable/25046339.

Recommendation. The OECD recommends issuing a binding regulation determining the exact conditions under which pecuniary financial advantages or benefits of significant value to doctors can be granted. This regulation should contain sanctions in case of infringement of the conditions. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 1983, as well as the CETIFARMA Code of Ethics, might be used as a starting point.

If this OECD recommendation is fully implemented, the benefit to consumers is estimated to be MXN 7 743.1 million. This calculation is explained in detail in Annex 2.A2.

2.3.1.2. Data records concerning retained prescriptions

To help steer their marketing efforts, pharmaceutical companies are interested in monitoring doctors' prescription practices. To do this, they generally find it helpful to acquire data about those practices that is as detailed as possible.

Description of the relevant obstacle. According to Article 117 of the Regulation on Health Inputs for Health, the pharmaceutical retailer registers in a control book or an automatised system the name, address and professional-licence number of the prescribing physician at the moment of the sale of medicines and this prescription is retained by the pharmacy. It is unclear what happens to this data and whether they might be sold directly or via specialised companies to pharmaceutical companies.

Harm to competition. If a pharmaceutical company could buy data about individual doctors' prescription practices, it would be able to monitor whether doctors prescribe its products and favour it over others. This would be harmful as there are currently no binding rules to clarify the conditions under which incentives can be granted to doctors by pharmaceutical companies. Theoretically, pharmaceutical companies could monitor the prescription practice of all active doctors and only incentivise those doctors (e.g. by inviting them to conferences) who mainly prescribe their products.

Policymaker's objective. The objective of the provision is to ensure a prescription's authenticity and to control a pharmacy's stock of prescription products (e.g. antibiotics, psychotropics and narcotics). This allows health authorities to control the stock of prescription drugs and ensure that they are only sold after a doctor has prescribed them.

Recommendation. The OECD recommends prohibiting pharmacies from passing personalised data from doctors or patients to pharmaceutical or any other companies (such as companies that collect and market data). Selling of aggregated data – data that do not allow the prescribing practices of individual doctors or the drugs used by an individual patient to be tracked back – should still be allowed, however, as they allow pharmaceutical companies to efficiently benchmark, plan and calculate their output and marketing efforts.

2.3.2. Generics

According to a definition by the US Food and Drug Administration, generics "are copies of brand-name drugs and are the same as those brand-name drugs in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use".[53] Potential competitors may copy a brand-name drug – also known as an innovative drug – and submit a series of tests to the relevant health authority to show the interchangeability of the copied drug with the referent one, either after the patent has expired, or even before that, in order to be ready to market a product immediately after the patent of the innovative drug has ended. In order to be considered as interchangeable, generics must prove their identity, strength, quality, purity, and potency, which is not allowed to vary considerably from the parameters of the referent medicine.[54]

Studies have shown that generics generally work as effectively as innovative drugs.[55] The proof of an interchangeable therapeutic effect between the generic drug and the innovative drug, within a permissible margin of variability, is one of the ends of interchangeability tests.

Entry of generics into the market usually leads to lower price levels and enhanced access to medicines. According to the OECD, generics typically sell for 30-50% below

their branded equivalent. In the United States, it is not unusual for a generic to achieve a 50% market share (by volume) within a year of the patent expiring (OECD, 2002: 37).

Theoretically, the prices of the original innovative drugs should decrease to the level of generics after generics enter the market (OECD, 2014: 10).[56] This is not always the case, however. Economic studies have shown that sometimes there are even considerable price rises for innovative drugs after the entry of generics.[57] Other studies have shown that the prices of innovative drugs do not decrease after the entry of generics (Frank, Richard G., and David S. Salkever, 1997: 75-90). Authors have called this phenomenon the "generic paradox", originating in the widespread perception that branded and non-branded drugs have a different therapeutic efficacy. In addition, this may be complemented in some jurisdictions by the presence of insurance contracts, which means that some consumers are not price sensitive.[58]

The OECD makes three recommendations for generics: concerning their prescription; the valuation rate that generic producers must meet; and the so called "linkage problem".

2.3.2.1. Mandatory sale of the branded drug, unless substitution is expressly permitted

Description of the relevant obstacle. According to Article 31 of the Regulation on Health Inputs, doctors can either prescribe an International Nonproprietary Name (INN; as defined by the World Health Organization, a unique, globally recognised name that is public property) or a jointly generic and distinctive designation, which is a mix of a generic drug and a brand name (e.g. salbutamol and "Ventolin"; ibuprofen and "Advil"; or paracetamol and "Tylenol"). When doctors prescribe a distinctive designation, pharmacists must comply with that designation; the medicine can only be substituted when the doctor expressly authorises it.

Harm to competition. Consumers are locked into purchasing a branded medicine if that is what is prescribed by the doctor. Generics may face a competitive disadvantage if doctors tend to prefer certain branded medicines and do not include generics in their prescriptions or authorise the substitution of the branded product. The harm to the consumer might be aggravated if doctors are not objective in their prescription practice, e.g. due to incentivisation of the pharmaceutical companies (see discussion under Incentivisation).

Policymaker's objective. The objective of this provision is to protect the Mexican population against sanitary risks.

There is a widespread belief in the Mexican population that generics are not as effective as the original drug (i.e. medicine protected by a patent or whose patent has expired). However, concerns over generics' safety and effectiveness compared to original medicines seem generally unfounded. Generics are therapeutically equivalent to the original medicine, and offer significant cost savings with no adverse health effects.

In a number of OECD member states (Denmark, Estonia, Finland, Germany, Italy, Slovak Republic, Spain and Sweden), pharmacists have to substitute a medicine with its cheaper alternative. For instance, in Italy since 2012, pharmacists have to substitute the innovative medicine with the lowest-priced generic, while in Sweden, they are obliged to substitute with the lowest-cost substitutable product unless the doctor states in the prescription that substitution is not allowed. In a majority of OECD countries, pharmacists are allowed to inform the patient about possible substitution and substitute

brand-name medicines with generics if the patient agrees and the prescribing doctor does not object in the prescription (e.g. Czech Republic) (OECD, 2016c: 30).

Also, several OECD member states require doctors to prescribe the generic denomination, e.g., Estonia, Portugal, Spain and France (OECD, 2016b: 182).[59]

Providing patients the possibility of choosing between the innovative or generic drug assures they benefit from the placebo effect: "Research has shown that a placebo treatment can have a positive therapeutic effect in a patient, even though the pill or treatment is not active (as long as the patient believes the treatment is taking place). This is known as the 'placebo effect' or 'placebo response'."[60]

Recommendation. The OECD recommends the following options to the Mexican government:

Option 1) Amend the provision in order to oblige pharmacists to inform patients about the cheapest available generic and allow the substitution of prescribed medicines with this generic when the patient agrees, unless the prescription specifically states "substitution not allowed" (which might be necessary if certain patients do not react well to substitutes of a certain medicine). The OECD recommends making the substitution optional, not mandatory, due to the fact that most customer purchases in Mexico are out-of-pocket spending and customers must be able to purchase the medicine they perceive to be best (placebo effect).

Option 2) Introduce a provision that requires doctors to prescribe only INN medicines, which is the active substance, but not the brand name.

If either of these OECD recommendations is fully implemented, the benefit to consumers is estimated to range between MXN 6 177.4 million and MXN 34 544.8 million. This calculation is explained in detail in Annex 2.A3.

2.3.2.2. Fixed percentage of valuation for interchangeability tests

Description of the relevant obstacle. According to the General Health Law, to be considered as generic, medicines must be interchangeable with a reference drug, i.e. the generics must produce the same therapeutic effect. In order to be considered as an interchangeable medicine the "percentage of valuation" of the test medicine must be within the limits stated in the Pharmacopoeia; this is a difference of up to 5% with the reference medicine.[61] The method of determining the 5% threshold is not clearly described (at least to the lay reader).

Harm to competition. The standard for the "percentage of valuation" may work as a barrier to entry for products that do not meet the 5% difference threshold. The rule might also be too inflexible, not taking account the specifics of each medicine. Some generics might only require a maximum difference of 1%, others 10% to perform the same function. From the disposition, it is not clear whether a margin of error applies. It is also not completely clear whether the Mexican test applied is equivalent to those of other jurisdictions, such as the European Union or the United States.

Policymaker's objective. The objective of this provision is to define the criteria and specifications that should be observed during the performance of the tests carried out to demonstrate the interchangeability of generic medicines. According to COFEPRIS the valuation rate could vary if the medicine is considered to be "variable". However, the NOM-177-SSA1-2013 does not provide a clear description of when a medicine is considered to be variable and which valuation rate would apply in that case.

International comparison. In the European Union, a generic medicine is defined as a medicine that "has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies" and "[f]ollowing the granting of a marketing authorisation, the authorisation holder may allow use to be made of the pharmaceutical, pre-clinical and clinical documentation contained in the file on the medicinal product, with a view to examining subsequent applications relating to other medicinal products possessing the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form".[62] In order to demonstrate bioequivalence, some characteristics are measured to prove that there is at least a probability of 90% that the results will fall between two values (i.e. the acceptance interval). The acceptance interval can be tighter or wider for some characteristics in special cases.

It might well be that the methodology currently applied in Mexico to determine equivalence conforms with international standards and avoids the problems described above in practice; however, several outside experts had difficulty in assessing that result, due to the lack of a clear description of the methodology.

Recommendation. The OECD recommends clarifying the methodology used to determine if a medicine can be considered as variable. Also, clarify if the applied method is equivalent to other jurisdictions (especially, the European Union and United States). The methodology should also be made easily available on the COFEPRIS website.

2.3.2.3. Linkage

Description of the relevant obstacle. When applying for a sanitary registry, a company needs to prove that it is the holder of the patent of the active substance or alternatively, that no patent will be infringed when producing the medicine in question. Once an application is received, COFEPRIS consults with the Mexican Institute of Industrial Property (Instituto Mexicano de la Propiedad Industrial, IMPI) to determine if there is any patent infringement. This is called "linkage".

According to industry participants, it is often unclear if the reference medicine is still protected by patents and if so, which patents they are. This is known as the "linkage problem". Although COFEPRIS and IMPI communicate to determine which patents are related to the medicine for which a company wants to offer a generic version and applies for sanitary registry, IMPI's current list of patents does not provide enough clarity and certainty to market participants.[63] There is a searchable version of the Official Gazette for medicine patents. However, market participants find it impossible to obtain definitive answers before they start producing generics. COFEPRIS and IMPI usually provide solutions on a case-by-case basis.

Harm to competition. According to market participants, the searchable version of the Official Gazette is difficult to use and does not always return all possible results. This contradicts the official COFEPRIS explanation.

The lack of sufficient information related to the patents protecting a certain medicine makes it more likely that pharmaceutical companies could unintentionally infringe a patent when manufacturing a generic medicine. In case of infringement, the producer would need to change the medicine formulation and again apply for a new sanitary registry with COFEPRIS.

Policymaker's objective. The objective of the linkage is to protect intellectual property rights and prevent sanitary registries being falsely granted – and in so doing, avoid the need to revoke them later due to infringement of existing patents.

International comparison. Other jurisdictions, such as the United States and Canada, have easily searchable online databases of the patents protecting specific molecules, and which drug is considered as the referent. The US government publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the Orange Book) identifies drug products approved by the Food and Drug Administration (FDA) and related patent and exclusivity information.[64]

Recommendation. The OECD recommends that COFEPRIS publish a list of all patents related to each medicine with a sanitary registry. The US Orange Book may serve as a blueprint.

In the future, companies asking for a sanitary registry might be required to provide a list of all patents they consider relevant to the medicine. This list could then be published by COFEPRIS. Generic producers would then be able to easily investigate which patents must be respected.

2.3.3 Adjacent Doctors' Offices (Consultorios Adyacentes a Farmacias, CAF)

More than half of all pharmacies in Mexico have adjacent doctors' offices or Consultorios Adyacentes a Farmacias (CAF). These are an important part of the Mexican health system as patients can access medical services promptly and at affordable prices or even for free. Nonetheless, these benefits do not come without risks as most adjacent offices are in some way funded or at least financially supported by pharmacies.

As previously indicated, a prescription model where doctors benefit from the price paid by the patient or the volume of medicines prescribed generates risks of unethical practices that may lead to excessive or sub-optimal prescription practices (OECD, 2014: 6-7). In this case, the risk stems from the relationship among the prescribing doctor with the pharmacy which the doctor works for. Adjacent pharmacies need funding to operate, and it seems likely that funds may come from excessive or sub-optimal prescriptions.

2.3.3.1. Legal lacuna concerning prescription practices of doctors working in CAF

Description of the relevant obstacle. According to COFEPRIS, in 2015, 53.5% of all pharmacies in Mexico have a CAF (COFEPRIS, 2015). CAF mostly belong to pharmacy chains. Consultations in these CAF are provided at affordable prices or even for free. While CAF business models may vary, most doctors working at CAF receive some form of compensation from the pharmacies, be it through a fixed salary, a bonus or some other form of remuneration.

CAF have shown a rapid expansion in Mexico as a result of the government's 2010 policy of discouraging self-medication. Known as the "Agreement to determine the guidelines for the sale and dispensing of antibiotics" ("Acuerdo por el que se determinan los lineamientos a los que estará sujeta la venta y dispensación de antibióticos"), it saw the Mexican authorities enact a prescription-only requirement to mitigate self-medication and control the dispensing of antibiotics.

To the best of our understanding, there is no provision that addresses the relationship between pharmacies and doctors, and limits the incentives pharmacies can provide to

CAF doctors for prescribing certain medicines. The Mexican Pharmacopoeia Supplement for Establishments[65] only forbids pharmacies to have "direct communication, through windows, doors or aisles, with other businesses, such as doctors' offices".

Harm to competition. As practically all CAF belong to pharmacies, doctors are not completely independent in their prescription practice. This could distort competition among medicines in three ways, as doctors could:

- prescribe the pharmacy's branded products (in the case where a pharmacy had its own brand of medicines) instead of, perhaps, the best-suited medicines
- prescribe products that might not be the ones that best fit consumers' needs, but which are in stock at the pharmacy and need to be used
- prescribe more products than needed (e.g. extra vitamins) if doctors receive payments linked to the quantity of products they prescribe.

These problems might be complemented by the inability of consumers to substitute branded drugs for generics. According to Mexican law, specific branded drugs prescribed by doctors cannot be exchanged by the patient or the pharmacist.[66] Hence, if doctors tend to prescribe a pharmacy's own brands or the pharmacy's preferred products (e.g. due to a bulk order of those medicines), some generics or even branded medicines may face a competitive disadvantage against the pharmacies' preferred products.

Policymaker's objective. CAF play an important role in Mexico's health system, assuring fast and affordable medical access to a significant part of the population.

International comparison. The practice of creating CAF has now been extended to countries including Guatemala, Chile and Argentina (Diaz-Portillo, Sandra. P. et al., 2015: 320-328). Many other countries, however, believe that doctors and pharmacists should remain independent of each other and so forbid the preference or sale of certain producers (e.g. for Germany, § 10 ApoG).

Recommendation. The OECD recommends the following three options for the Mexican government. Options 1 and 2 are possible as stand-alone solutions, but could also be combined; Option 3 would mean keeping the status quo, leaving the current CAF business model unchanged.

Option 1) Issue a provision prohibiting CAF doctors from prescribing branded products and mandate them to prescribe only the INN or the generic name. This solution was discussed in the Generics section above. Patients would be able to choose the drug they consider the best in terms of price or quality from different medicines. This option would solve the problem of CAF doctors prescribing expensive branded drugs. However, it would not solve the problem of over-medication when those doctors prescribe more drugs than necessary.

Option 2) Issue a code of conduct or regulation prohibiting pharmacies from exerting pressure on or incentivising doctors to prescribe certain products, especially by rewarding the volume or number of medicines prescribed. As pharmacies would not be able to influence doctors' prescription habits, irrational prescription patterns (e.g. prescribing specific brands instead of generics or prescribing unnecessary products) would disappear. However, this solution might change the existing business models of CAF. Pharmacies' incentives to invest in CAF might be reduced and CAF might have to raise fees for their services. Indeed, many CAF might even close if they were no longer cross-subsidised by pharmacies.

Option 3) No recommendation. The policymakers' objective of granting quick and easy medical access for the Mexican population might take preference over any possible conflict of interest. This recommendation would leave the current CAF business model unchanged.

2.3.4. Direct sales by pharmaceutical companies to pharmacies (especially pharmacy chains)

Pharmaceutical companies generally use wholesalers to deliver their medicines to retailers, especially to small vendors (OECD, 2014: 20). Wholesalers are middlemen between pharmaceutical companies and retailers, bulk-buying drugs from the former and reselling them in smaller quantities to the latter. Since not all retailers have enough capacity to stock all the drugs they may require, wholesalers ensure regular drug deliveries and usually provide a number of related services, such as inventory and stock management, treatment of expired products, and support in storing patient information (OECD, 2014: 20).

Wholesalers either buy, stock, and deliver all type of medicines or just specialise in a selection of drugs. The first are known as full-line wholesalers; the second, short-line wholesalers. Full-line wholesalers tend to compete for consumers, offering frequent delivery and low prices; short-line wholesalers tend to offer less frequent delivery and lower prices (OECD, 2014: 20). It is relatively common for jurisdictions to require wholesalers to follow the full-line model to ensure continued availability of medicines to the general public. This is the case in most EU member countries, where the distribution of medicines is considered a public-service function (European Association of Pharmaceutical Full-Line Wholesalers, 2015: 1).

For pharmacies, it may be costlier to deal with short-line wholesalers, since this model requires dealing with multiple financial relationships and multiple deliveries. As previously mentioned, in some European countries the law requires distributors to follow the full-line model. This stems from the public-service nature of medicine wholesaling. Yet, even in EU member states, the interpretation of this obligation varies.

The full-line model in Europe does not stop the parallel operation of different distribution models. Agency (or direct-to-pharmacy) arrangements may coexist with reduced-wholesaler arrangements, according to which manufacturers can completely (in the case of agency) or partly (in the case of a reduced-wholesaler model), or a combination thereof, avoid the traditional supply chain and supply pharmacies directly (Kanavos, Panos, W. Schurer, & S. Vogler, 2011: 75).

Distributors can be independent or have exclusive arrangements with particular manufacturers meaning that only one distributor can market certain drugs. In a growing number of jurisdictions manufacturers have vertically integrated, providing services related to stock, demand managements, and direct sale to pharmacies (OECD, 2014: 22). Indeed, in several countries, wholesalers as described above no longer exist (e.g., US, Canada and Chile) (Kanavos, Panos, W. Schurer, & S. Vogler, 2011: 32). In many other jurisdictions, the wholesale level is extremely concentrated.[67] This is also the case in Mexico.

In this section, the OECD makes one recommendation in order to enhance competition in the distribution segment of the market, namely to introduce an obligation to supply full-line wholesalers.

Description of the relevant obstacle. The wholesale and retail sale of medicines and other health products, narcotics, psychotropic substances, and products containing narcotic or psychotropic substances requires a sanitary authorisation (i.e. licence).[68] The sanitary authorisation for manufacturing medicines granted to pharmaceutical companies is not limited to the manufacturing. There are therefore no provisions prohibiting direct selling by pharmaceutical companies to pharmacies.

However, in practice, many (if not most) pharmaceutical companies in Mexico refuse to sell directly to pharmacies, even to large pharmacy chains, but prefer selling through wholesalers. It is common practice for pharmaceutical companies to sign exclusive contracts with one distributor. Thus, wholesalers often become the only channel used to commercialise a certain medicine. According to industry participants, pharmaceutical companies usually pay a service fee to distributors when they sell their products (a scheme known as "fee for service").

This situation concerns the private market as in the public market authorities generally purchase medicines through public tenders.

Harm to competition. For the largest retailers (i.e. pharmacy chains), buying from a wholesaler imposes an unnecessary cost, as they have to pay an extra margin to wholesalers instead of acquiring the products directly from the producers. Also, market participants at retail level complain that many medicines are distributed by only one wholesaler and there is no, or only very limited, intra-brand competition.

Policymaker's objective. According to COFEPRIS, direct sales from pharmaceutical companies to pharmacies are not restricted. The sanitary licence granted to a pharmaceutical company to manufacture medicines can include, among other listed activities, the distribution of medicines. If distribution is not included, it is easy to make changes to the sanitary licence.

International comparison. European Union law sees wholesalers as having a "public-service function".[69] That means that full-line wholesalers that provide all relevant medicines have to be supplied by pharmaceutical producers so national coverage of the population with adequate medicines is guaranteed. The public-service function is applied in different ways throughout the EU; some countries (e.g. Germany), however, have introduced a quasi-obligation to supply all full-line wholesalers.[70]

The obligation to supply wholesalers does not exclude direct supply of pharmaceutical companies to pharmacies.

Recommendation. The OECD recommends that Mexico considers introducing an obligation for medicine producers to supply all full-line wholesalers in the private market, which would have the aim to allowing new wholesalers to compete. Before moving forward with such a measure however it is recommended that a study in coordination with the relevant authorities assesses the impact on the market of introducing such an obligation, whose purpose would be to allow new wholesalers to compete in the concentrated Mexican wholesale market and increase intra-brand competition. However, as this proposed recommendation would interfere with contractual freedom, it should only be implemented if such study would demonstrate that other measures to strengthen intra-brand competition do not lead to any results.

If an obligation for medicine producers to supply all full-line wholesalers in the private market were to be implemented, the benefit to consumers is estimated to be

between MXN 128.1 million and MXN 3 074.6 million. This calculation is explained in detail in Annex 2.A4.

2.3.5. Price Regulation

Drugs are essential to human health and even survival. Patients tend to be insensitive to the prices of drugs, at least when medicines treat serious medical conditions. Due to this lack of price elasticity for medicines and the market power held by many manufacturers of original drugs, pharmaceutical prices are regulated in many countries at various level of the supply chain.[71]

Pharmaceutical products are also considered "merit goods", meaning patients should be able to acquire them irrespective of their ability to pay for them.

Price regulation faces the challenging task of assuring access to medicines on the one hand, without distorting incentives to invest and market products on the other hand. Worldwide, there are two main approaches to price regulation of patented medicines. The first, usually known as "international reference pricing" or external reference pricing (ERP), consists of setting maximum prices according to the prices charged in other countries for the same drug. The second, named "internal reference pricing" regulates maximum prices taking account of prices of other drugs from the same therapeutic class within the same country. Mexico follows the first approach (OECD, 2014: 11).

In this section, the OECD makes two recommendations. Firstly, amending the current price-regulation system for patented medicines, and secondly, publicising the mechanism that determines how maximum prices are set.

2.3.5.1. Maximum prices for patented drugs

Description of the relevant obstacle. A 1996 agreement between the Ministry of Economy and CANIFARMA (amended in 2004) establishes maximum retail prices for patented medicines. The maximum price for a patented medicine in Mexico is determined as the average of the ex-manufacturer price of that medicine in the six countries with the largest sales in the world.

Harm to competition. Having maximum prices for patented drugs raises several potential competition problems. First, the agreement mentioned above restricts the ability of firms to choose prices freely. Second, considering the labelling duty to inform about maximum prices on the packages of a medicine (as discussed in Section 2.3.10), this provision may facilitate collusion and restrict competition at the retail level. Third, and most importantly, the current price-setting mechanism seems to result in high final prices in the Mexican market, especially when compared with other Latin American countries. This might be due to the current price-regulation system's tendency to focus on high-income countries as a benchmark. Maximum prices are determined based on the average of the six countries with largest sales in the world, but these countries are often also the countries with comparatively high prices. For example, in 2005, the United States, Japan, Germany, France, Italy, and the UK were the six countries with the largest expenditure on pharmaceuticals.[72]

Policymaker's objective. The objective of the agreement is to protect Mexican consumers from pharmaceutical companies charging excessive prices, as well as to promote investments in pharmaceutical development, by assuring the participation of the industry in the setting of maximum prices.

The World Health Organization (WHO) reports that in 2015, 24 out of 30 OECD member states used a pricing system based on ERP with varying reference proxies (World Health Organization, 2015: 14). The WHO recommends applying ERP only in combination with other methods, however, as ERP alone may lead to inappropriate final prices, especially if reference countries are badly chosen (e.g. if the reference countries have substantially different market structures or prices) (World Health Organization, 2015: 15). For example, in Canada, ERP is used together with other criteria, such as the sale price of medicines in relevant markets; the prices of other drugs from the same therapeutic class in relevant markets; the prices of the same medicine and other medicines in the same therapeutic class in specific foreign comparison countries (namely, France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States); and changes in the Consumer Price Index (Daley, J., 2010).

Recommendation. The OECD recommends rebuilding the basket used to calculate maximum prices for Mexico, taking into account not only sale volumes (as it does currently), but also other factors, such as income level of reference countries and out-of-pocket expenditures. In addition, the basket should be periodically revised – for example, every five years – to ensure that it satisfies the needs of the Mexican population.

2.3.5.2. Confidentiality of the amendment to the CANIFARMA and Ministry of Economy agreement

Description of the relevant obstacle. The original maximum-price agreement between the Ministry of Economy and CANIFARMA is available to the public. In 2004, however, it was amended and, according to Mexican transparency law, this amendment remains confidential. There does not seem to be a plausible justification for keeping this document secret and no objective was found in law. Its confidential nature makes it impossible for the public to assess its contents and look for mechanisms that may lower prices for the Mexican consumer. The OECD recommends making public both the agreement and any modifications.

2.3.6. Authorisations

The pharmaceutical sector is heavily regulated. The manufacturing of medicinal products requires strict ex ante control to ensure the protection of public health and that chemical products with therapeutic utility provide the expected benefits. In addition, the distribution and sale of medicines is subject to strict control to monitor retailers.

Authorisations can impose a non-negligible cost on market participants. If entry is too burdensome, this may prevent potential competitors from entering the market and impose higher degrees of competitive pressure on incumbents. Thus, legislators should make sure that authorisation processes do not become more onerous than is necessary to achieve the sought regulatory objectives (OECD, 2016a: 13).

In this section, the OECD makes seven recommendations concerning the renewal of sanitary registries; sanitary registries for biosimilar products and requests for new studies; how to determine the reliability of dogs and cats used for scientific research; the discretion to grant reductions in the frequency of analytical tests for inputs used in the manufacture of medicines in Mexico; the possibility of making applications online; and the applicability of the Reglamento de la Ley General de Salud en Materia de Control Sanitario de Actividades, Establecimientos, Productos y Servicios.

2.3.6.1. Renewal of sanitary registries

Description of the relevant obstacle. Sanitary registries need to be renewed every five years. According to Article 195-A of the Federal Fees Law (Ley Federal de Derechos), for a sanitary-registry renewal, applicants shall pay 75% of the new sanitary-registry fee. The sanitary-registry fee for generics currently costs MXN 71 334.41 and for new molecule medicines MXN 127 549.79.

Harm to competition. Requiring that the sanitary registry is renewed every five years imposes an extra cost on firms. The costs can be quite significant for producers that are often marketing several hundreds of products.

Policymaker's objective. The objective of this provision is to protect the Mexican population against sanitary risks. During the renewal period of sanitary registries, the Ministry of Health examines the same aspects as examined during the first application for a sanitary registry. According to COFEPRIS, in more than 50% of all applications for renewal of the sanitary registry, the companies do not meet the necessary requirements to obtain or renew the sanitary registry.

International comparison. In the European Union, a marketing authorisation is valid for five years and may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the competent authority of the authorising member state. Once renewed, the marketing authorisation shall be valid for an unlimited period.[73] In the Proposal for a Regulation of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products,[74] the European Commission even suggested that the marketing authorisation should be valid for an unlimited period. Concerning the EU comparison, COFEPRIS pointed out that EU member states generally have a different supervision system and carry out more visits in-situ, which currently might not be possible for COFEPRIS to implement due to a lack of resources.

A different system is applied in the United States, where marketing authorisations (known as New Drug Applications) are granted once for an unlimited time, but the final product is reviewed once a year through an annual report for minor changes.[75]

Recommendation. The OECD recommends that the sanitary registry should be renewed only once after five years and then be perpetual. The OECD team agrees with COFEPRIS that such a change in system should only be implemented after the Mexican control and supervision system has been significantly improved. This would require increasing the frequency of in-situ controls; introducing large fines if pharmaceutical companies do not report changes in a medicine in time to COFEPRIS; and granting adequate resources to COFEPRIS to fulfil this task.

If this OECD recommendation is fully implemented, the benefit to consumers is estimated to amount to MXN 4.8 million. This estimation does not take into account the internal savings (preparation of documents etc.) that pharmaceutical companies will experience if they do not have to perform every five years all the tests presented when the sanitary registry was granted. Also, the annual costs related to the annual revisions might be underestimated. A significant improvement of the Mexican control and supervision system will bring additional costs which will probably have to be carried by the pharmaceutical companies. This calculation is explained in detail in Annex 2.A5.

2.3.6.2. Sanitary registries for biosimilar products and requests for new studies

Description of the relevant obstacle. Producers need to apply to the Ministry of Health in order to obtain a sanitary registry for biosimilar products. In addition to the normal requirements specified in the regulation, the Ministry of Health can impose additional requirements, such as tests and studies for the registry of biosimilar medicines. The Ministry of Health establishes these requirements upon hearing the recommendation of the Committee on New Molecules, which in turn consults the Biotechnological Products Assessment Sub-Committee (Subcomité de Evaluación de Productos Biotecnológicos, SEPB).

Harm to competition. Authorities are granted a large degree of discretion, as they operate on a case-by-case basis. The requirements imposed on companies might vary and so discriminate between them.

Policymaker's objective. Biotechnological products are relatively new products that pose various risks. The Mexican government has therefore put up various additional requirements for those products with the aim of protecting the Mexican population against health risks.

Recommendation. The OECD recommends issuing guidelines that specify in which cases it is necessary to fulfil additional requirements to obtain a sanitary registry for biosimilar products. These guidelines would reduce the degree of discretion in granting sanitary registries for biosimilar medicines. This solution presupposes that it is possible as the nature of biotechnological products means requirements for the sanitary registry of biosimilar medicines may vary according to the product.

2.3.6.3. Reliability of suppliers of cats and dogs used for scientific research

Description of the obstacle. All dogs and cats used in scientific research, technological development and innovation, laboratory testing and teaching, must be obtained from suppliers that are considered to be reliable by the Committee for the Care and Use of Laboratory Animals (an internal committee that each company carrying out research must have). To the best of our understanding no provisions or guidelines exist that establish how the reliability of suppliers is to be determined.

Harm to competition. This provision restricts the offer of available dogs and cats used for scientific research; this might raise prices of an important input.

Policymaker's objective. The objective of this provision is to ensure that animals are given adequate treatment and care, so they are not stressed, which would make them susceptible to disease.

International comparison. The authorisation seems to be in line with international practice. For example, in the European Union, the use of animals taken from the wild for medical tests should be limited to cases where the purpose of the test cannot be achieved using animals bred specifically for this use.[76] Member states must ensure that all breeders, suppliers and users are authorised by, and registered with, the competent authority. Such authorisation may be granted for a limited period. Authorisation shall be granted only if the breeder, supplier or user and its establishment is in compliance with the law.

Recommendation. Publish binding guidelines with criteria to determine whether a supplier is reliable.

2.3.6.4. Discretion to grant reductions in the frequency of analytical tests for inputs used in the manufacture of medicines in Mexico

Description of the relevant obstacle. Article 10.2.3.2.5 of NOM-164-SSA1-2015, "Buenas prácticas de fabricación de fármacos", sets the minimum requirements necessary to manufacture medicines' inputs, such as how often a process should be monitored. In order to reduce frequencies and/or the analytical tests for the inputs used in the manufacture of medicines in Mexico, a medicine manufacturer must receive an authorisation from the Ministry of Health. If the authorisation is granted, according to "Procedimiento normalizado de operación para reducción de la frecuencia de muestreo y de las determinaciones en materia prima y/o producto terminado no biológico", a document issued by the Ministry of Health, the manufacturer receives an official letter of authorisation for decreasing the sampling frequency. This authorisation has a validity of three years.

Harm to competition. To the best of our understanding, there are no clear guidelines with regard to granting such authorisations; this might lead to unequal treatment between producers.

Policymaker's objective. The objective of this provision is to minimise administrative burdens and set the minimum requirements necessary for the manufacturing process of medicines to be commercialised in Mexico.

Recommendation. The OECD recommends clarifying in the NOM the criteria and procedure to modify frequencies of control and analytical tests.

2.3.6.5. Electronic submissions to COFEPRIS

Currently, only around 20% (70 of 365) of all applications to COFEPRIS can be made electronically. The impossibility of submitting applications to Mexican authorities this way raises administrative costs for companies. COFEPRIS has an ongoing project to allow more electronic applications. In a recent report, the World Economic Forum concluded (not only for the medicine industry, but in general) that administrative processes in Mexico can be slow and they may affect trade.[77] The OECD recommends continuing with the ongoing project to allow the electronic submission of all applications to COFEPRIS or the corresponding authority.

2.3.6.6. Unclear scope of Reglamento de la Ley General de Salud en materia de control sanitario de actividades, establecimientos, productos y servicios

Some articles of the Reglamento de la Ley General de Salud en materia de control sanitario de actividades, establecimientos, productos y servicios refer to health inputs, narcotic and psychotropic substances and medicines. According to COFEPRIS, this regulation does not apply to medicines. However, this is not clear in the law's text. This lack of clarity may increase search costs for companies. The OECD recommends amending this regulation to delete references to medicines.

2.3.6.7. Difficulty to find official guidelines on the COFEPRIS website

Currently, various guidelines issued and used by COFEPRIS are difficult to find on its website. For example, in June 2017, the "Lineamientos que deberán cumplir los medicamentos alopáticos de referencia y selección de medicamento de referencia internacional" and "Lineamientos que establecen los requisitos que se deben cumplir para

la acreditación de los certificados de buenas prácticas de fabricación para la solicitud de modificaciones, prórrogas y registros sanitarios de medicamentos" were impossible to find. This difficulty may increase companies' search costs. The OECD therefore recommends revising the COFEPRIS website to make easily available all guidelines that pharmaceutical companies must follow, and constantly update the list.

2.3.7. Imports and exports

Medicines are tradable goods that can be imported and exported from one country to another. The import of medicines may bring considerable cost savings to patients in one country because importers can be an important alternative source of supply. However, due to public-health concerns, international trade in medicines is subject to strict regulation as imported medicines should not be of worse quality, safety and efficacy than those produced in the internal market.

Parallel imports differ from standard imports in that they concern goods authorised for sale in one country by the manufacturer that owns the relevant intellectual property rights, but which are subsequently imported into another country without the original manufacturer's authorisation and compete in this market with authorised imports (OECD, 2014: 19). In this sense, parallel trade may encourage intra-brand competition (OECD, 2014).

In the area of imports, the OECD makes one recommendation concerning registries to import medicines.

2.3.7.1. Requirement to count on the registry holder's permission to import medicines into Mexico

Description of the relevant obstacle. A registry with the Ministry of Health is required before importing pharmaceutical products for commercial purposes. If a potential importer is not the holder of the registry, it must obtain the consent of the owner before it can get an authorisation from the Ministry of Health to begin importing.

Harm to competition. The incumbent importer can prevent market entry of other importers. The law grants the first holder of the registry a de facto monopoly since it will generally not have an incentive to authorise potential competitors and allow intra-brand competition.

Policymaker's objective. The law does not mention any specific objective. However, a possible justification may be to assure the traceability of medicines and facilitate their control and the eventual imposition of liability in case adverse effects emerge.

Traceability, however, can also work with more than one importer, as current labelling regulations require a mention of the importer's identity.

Recommendation. The OECD recommends abolishing this restriction. Every importer should be able to get an authorisation from the Ministry of Health, independently of the consent of the incumbent holder of a registry. Additional importers should not have to fulfil the same documentation requirements as the first importer for acquiring a registry as the safety of the imported drug will have been proved by the first application already. However, the first importer that has to bear the costs for providing all required documents for the registry to import the drug for the first time might be granted a limited time of exclusivity by law (alternatively, this could be left to private exclusivity agreements between foreign pharmaceutical producers and importers).

2.3.8. Discrimination against foreign companies

This section describes provisions that potentially discriminate against foreign companies. Here, the OECD makes three recommendations: concerning clinical studies for biotechnological innovative medicines; interchangeability tests; and origin denomination for the sale of ethyl alcohol.

2.3.8.1. Geographic requirement for clinical studies for biotechnological innovative medicines

Description of the relevant obstacle. To be granted a sanitary registry by the Ministry of Health, pharmaceutical companies must conduct clinical studies. For biotechnological innovative medicines, these clinical studies must take place in Mexico when the medicine is produced in Mexico. If the medicine is produced abroad, the Ministry of Health, based on the opinion of the New Molecules Committee, can request additional tests in Mexico.

Harm to competition. This rule imposes extra costs on foreign companies as they may have to perform medical studies twice, once in their home country and then again in Mexico.

In addition, according to pharmaceutical industry participants some of the tests are excessive (i.e. phase II and III) and require the participation of a large number of Mexican patients. Finally, there is a risk of discretion from the Ministry of Health when deciding whether or not to require additional internal tests to companies producing abroad.

Policymaker's objective. A possible justification for the provision may be that the Mexican authorities seek to ensure that a medicine is suitable for the Mexican population. According to COFEPRIS, studies must be performed in Mexico when foreign biotechnological producers choose Mexico as the country where the product will be registered for the first time. For biosimilar products, Mexican authorities accept foreign studies as long as medicines are similar.

Recommendation. The OECD recommends amending the provision so that, unless Mexico is the first country where the medicine is marketed, the sanitary registry of biotechnological products is not conditional on studies conducted in Mexico if the company has already conducted studies abroad, as long as the foreign country's control system is regarded as at least equivalent to the Mexican. Only in exceptional cases, in which the effects of drugs may vary due to phenotypic differences in the Mexican population, should the Ministry of Health order additional tests in Mexico. This exception should be made explicit in guidelines.

2.3.8.2. Geographical and population requirements for interchangeability tests

Description of the relevant obstacle. Interchangeability tests (i.e. tests performed to determine whether a generic medicine produces a similar effect to the reference product) must be performed by authorised third parties on Mexican territory and with a Mexican population sample.

Harm to competition. This requirement may impose unnecessary extra costs on pharmaceutical companies that operate abroad, discouraging them to sell generic medicines in Mexico. For example, a pharmaceutical company that has already performed interchangeability tests in the United States before introducing a generic there and then

later wishes to introduce the same product in Mexico would have to perform the interchangeability test again in Mexico, with a Mexican population sample.

Policymaker's objective. The NOM-177-SSA1-2013 does not mention any specific objective. However, a possible justification may be that the Mexican authorities are seeking to ensure that a medicine is suitable for the Mexican population. As with the restriction discussed above, there may be the cases when the population characteristics of other countries do not coincide with those of Mexicans and that Mexicans respond differently to a certain medicine. However, the OECD considers this scenario to be an exception and not the rule.

International comparison. Similar policy considerations do not seem to exist in European or American legislation.

Recommendation. Similar to the recommendations discussed before, the OECD recommends abolishing the requirement that pharmaceutical companies conduct tests on Mexican territory and population samples, and that the authorities accept interchangeability studies that have been granted by foreign authorities as long as their control systems are regarded as at least equivalent to the Mexican one. COFEPRIS should recognise those authorities, in the same way as it has recognised the right of eight foreign authorities to issue Good Manufacturing Practice certificates. Only in exceptional cases for which there must be guidelines, may the Ministry of Health order special additional tests with Mexican population samples.

2.3.8.3. Origin denomination for the sale of ethyl alcohol

The packaging of ethyl alcohol (used as a disinfectant) should clearly feature the following mention on the label: "HECHO IN MÉXICO" ("MADE IN MEXICO"). The objective of the provision is to provide consumers with clear information on ethyl alcohol and the conditions for its safe use. However, as this requirement applies to all packages of ethyl alcohol commercialised in Mexico, foreigner companies producing ethyl alcohol might be excluded from the Mexican market. The OECD therefore recommends abolishing the section of the NOM requiring the MADE IN MEXICO label in order to allow foreign producers of ethyl alcohol to participate in the Mexican market.

2.3.9. Advertising

Companies advertise their products to remain visible in the marketplace and gain market share.[78] Incumbents may need to advertise their products to avoid consumers switching from one brand to another or in order to gain business from its rivals. For newcomers to a market, advertising may even be more important so they can reach and inform potential customers (OECD, 2016a: 16). Consumers will have no experience with respect to the nature and quality of new products, so sellers will need to induce consumers to purchase them, probably switching from an already known competitor. Without advertising, consumers may not have enough information to engage in such behavioural change. Advertising is crucial for market penetration and market competition.

Nonetheless, in the medicines sector advertising can have negative side-effects. Advertising may encourage self-medication, as well as lead people to believe they may have symptoms mentioned in advertising campaigns. Because of this, advertising in most countries is restricted to over-the-counter medicines. For prescription medicines, pharmaceutical companies may only inform doctors (and in some countries also

pharmacists) of their products and their effects, so the latter consider patients' best interest when prescribing medicines.

In this section, the OECD makes five recommendations, concerning advertising authorisations; the targets of advertising; the possibility of mandate additional warnings in advertising; advertising of biotechnological products; and the use of the results of PROFECO's investigations in advertising campaigns.

2.3.9.1 .Advertising of medicines restricted to health professionals

The advertising of prescription drugs in Mexico is only allowed when it targets health professionals. It is not allowed to be aimed at final consumers or pharmacies. This restriction might make it difficult for market participants to gain market share and may especially place new entrants at a competitive disadvantage.

A likely objective of the restriction may be to discourage people to acquire a medicine that might relate to symptoms they believe to have. Similar restrictions exist in most other jurisdictions. For example, in European Union law, advertising of prescription medicinal products to the general public is banned in member states.[79] Only in the United States and New Zealand is direct-to-consumer advertising allowed.

In the European Union, advertising to pharmacists is permitted, however. This can be especially important for new generic producers trying to reach pharmacists and convince them to substitute patented drugs or branded generics with their product. The OECD recommends allowing advertising targeted at pharmacists, especially after it becomes possible for pharmacists to substitute the medicine prescribed by doctors for one with the same therapeutic effect.

2.3.9.2. Ex ante authorisation to advertise medicines

Description of the relevant obstacle. Advertising about the availability, quality and features of medicines, as well as promoting the use, sale or consumption directly or indirectly of health products, requires previous authorization from the Ministry of Health.

Harm to competition. This provision may prevent incumbents, as well as potential entrants, from gaining market share, by limiting free advertising. Ex ante control delays advertising and imposes an administrative burden on the producer and the administration.

Policymaker's objective. The objective of the law is likely to ensure the validity of the statements provided to health professionals in advertisements.

Generally, control of advertising is possible ex ante or ex post. In Europe, for example, advertising generally does not have to be authorised ex ante, but is subject to strict ex post control. Advertisers are subject to fines in case of breaching the regulatory requirements. [80]

Recommendation. The OECD recommends abolishing ex ante authorisation system and controlling advertising ex post, under a liability regime. Fines should be introduced in case of regulatory breach to guarantee compliance of pharmaceutical companies.

2.3.9.3. Unregulated ministerial power to mandate additional warnings in advertising

The Ministry of Health can mandate additional warnings in the advertising of these products. The law does not further specify on the conditions or content of those warnings.

The provision therefore provides the authorities with a high degree of discretion. Additional warnings may channel demand towards a certain product while discriminating against other producers. The objective of this provision consists of providing consumers with an accurate description of the risks that medicines may impose on them. The OECD recommends issuing guidelines that specify in which cases additional warnings are allowed (ex ante or ex post) and ensure that they are then applied on a non-discriminatory basis.

2.3.9.4. Restricted advertising for biotechnological products

Advertising for biotechnological products may not use qualifiers that present them as superior to conventional products or to similar products not obtained biotechnologically. This provision forbids comparisons based on objective facts and so may restrict the competitive pressure between biotechnological products and conventional products, since comparison is one of the key elements of advertising. A possible reason for the restriction might be that biotechnological products are more expensive for buyers, involve more complex and riskier production methods, and are still subject to intensive research. The OECD team was not able to identify similar advertising rules for biotechnological products in other jurisdictions, showing that those rules are not absolutely necessary to reach the policymakers' objective. The OECD therefore recommends abolishing this provision, allowing comparison on an objective basis within the constraints of comparative-advertising provisions in Mexican law.

2.3.9.5. Impossibility of using the results of PROFECO's reports as advertising

The Mexican Federal Attorney's Office of Consumers (Procuraduría Federal del Consumidor, PROFECO) produces and publishes reports on the quality and features of products and services, in order to guide and protect consumers. In these reports, PROFECO makes specific mention of brands. However, Article 44 of the Federal Law on Consumer Protection forbids companies from quoting these reports. The provision limits the freedom of suppliers to use public information to advertise their products, even when this information is based on objective grounds.

According to anecdotal evidence, the goal of the provision is to guarantee PROFECO's independence by preventing companies from trying to exert undue influence on the authority, as well as to prevent them from misquoting PROFECO's report (e.g. "recommended by PROFECO"). However, these goals can also be reached without restricting competition. The OECD recommends abolishing Article 44 of the Federal Law on Consumer Protection, since these concerns appear unjustified as the law already contains an article that forbids misleading or abusive advertising.[81] At the same time, measures should be taken to guarantee the independence of PROFECO officials from lobbying efforts and ensure that there are efficient mechanisms (including sanctions) in place to avoid misleading advertising.

As PROFECO's reports do not only deal with medicines, but with all industries, the same recommendation is made in this report concerning meat.

2.3.10. Labelling

Labelling laws ensure that pharmaceutical products are properly labelled so that patients can find relevant information before purchase (e.g. the name of the product and its expiration date) and during treatment (e.g. side effects). In this report, the OECD makes only one recommendation concerning contradictory norms on re-labelling.

2.3.10.1. Contradictory norms on relabelling

According to the Reglamento de la Ley General de Salud en Materia de Control Sanitario de Actividades, Establecimientos, Productos y Servicios, imported products packaged at the origin country are allowed to keep their original labelling if they also have an additional label containing all the requirements indicated in Mexican law. The NOM-072-SSA1-2012, Etiquetado de medicamentos y de remedios herbolarios, however, states that it is forbidden to relabel on the top of original information.

The two quoted provisions contradict each other. According to COFEPRIS, the first quoted Regulation does not apply to medicines. However, this is not clear in the text of the provisions. The OECD therefore recommends clarifying the Reglamento de la Ley General de Salud en materia de control sanitario de actividades, establecimientos, productos y servicios to clarify that it does not apply to medicines and delete all references to medicines in this provision.

2.3.11. Pharmacopoeia

A Pharmacopoeia is an official publication containing a list of medicinal drugs with their effects and directions for their use. Mexico has issued its own Pharmacopoeia since 1846.[82] In this area, the OECD makes three recommendations about lifting discriminatory provisions against foreigners; making the Pharmacopoeia available online; and providing guidelines about which sources to follow if the Mexican Pharmacopoeia is silent on a particular topic.

2.3.11.1. Discrimination against foreign buyers

The Mexican Pharmacopoeia is 50% more expensive for purchasers paying in US dollars: USD 760 vs. MXN 8 600 (or USD 473, at 11 June 2017 exchange rates). Entry to the market is thus slightly costlier for companies paying in US dollars, which will mostly be foreign companies. The OECD therefore recommends applying the same price for all subscribers independently of their nationality or their chosen currency.

2.3.11.2. The Mexican Pharmacopoeia is unavailable online

The Mexican Pharmacopoeia is not currently available online. Companies therefore have to acquire a hard copy, which might delay entry. Market participants have indicated that they have experienced no significant problems with acquiring hard copies of the Pharmacopoeia, though they would prefer an online version. COFEPRIS has already started a project to make the Pharmacopoeia available online. The OECD recommends continuing this project and making the Pharmacopoeia available online as soon as possible.

2.3.11.3. Lack of clear guidelines about the correct sources to use when the Mexican Pharmacopoeia does not regulate

Several dispositions concerning Mexican health law specify that when the Mexican Pharmacopoeia does not regulate a particular issue, foreign pharmacopoeias and other sources of scientific international information may be used. These norms create uncertainty, however, as no clear rules apply when the Mexican Pharmacopoeia is silent on a particular matter. Though market participants indicated that this is not considered as a serious problem, as there is an informal agreement in place on which other sources of information can be considered as valid, the OECD recommends compiling a list of

specific alternative documents that market participants could consider as sources of authoritative knowledge in case of the Mexican Pharmacopoeia not covering a topic.

2.3.12. Non-harmonised standards

Description of the obstacle. In our review of medicine legislation, the OECD found 10 NOMs that contain statements that are not in line with international norms.

These were:

- NOM-073-SSA1-2015, on stability of drugs and medicines and herbal medicines
- NOM-177-SSA1-2013, on tests and procedures to determine when a medicine is interchangeable
- NOM-249-SSA1-2010, on sterile mixtures and their preparation
- NOM-257-SSA1-2014, on biotechnological medicines
- NOM-012-SSA3-2012, establishing criteria for research projects involving humans
- NOM-248-SSA1-2011, on good manufacturing practices for establishments dedicated to the production of herbal medicines
- NOM-164-SSA1-2015, on good manufacturing practices of medicines
- NOM-138-SSA1-1995, on sanitary specifications for denatured, antiseptic and germicide alcohol
- NOM-072-SSA1-2012, on labelling of medicines and herbal medicines
- NOM-062-ZOO-1999, on technical specifications for the production, care and use of laboratory animals.

Harm to competition. Non-harmonisation with international standards – be it partial or total – may hinder foreign competitors' access to the Mexican market, as well as Mexican producers' access to foreign markets. In particular, producers might have to apply different sets of norms in Mexico and abroad, which might lead to extra costs.

Even if national standards have recently been (partially) adapted to international standards, if the legal text is not updated, this might lead to confusion among market participants.

Policymaker's objective. There is no underlying objective behind the non-harmonisation of NOMs. In Mexico, Article 41, Letter VI of the Federal Law on Metrology and Standardisation states that the non-harmonisation of NOMs must be disclosed and that NOMs must have the degree of accordance with international norms and criteria.

Recommendation. For all norms, the OECD recommends updating all NOMs so that they are, as far as possible, in line with international standards. Some current practices may already be in accordance with international standards, which might ease the transition. The law should also point out the cases in which no international standards or best practices exist.

2.3.13. Various

The following section describes various problems that do not fall under any of the headlines above. In total, the OECD makes six recommendations. These cover issues such as distance regulation for pharmacies operating inside retail stores; size regulation for the sale of denatured ethyl alcohol; academic members part of the Committee on New Molecules; and the voting system to reform the Internal Regulation of the Commission to define treatments and medicines associated with diseases causing catastrophic expenses.

2.3.13.1. Distance regulation for pharmacies operating inside stores

Description of the relevant obstacle. Pharmacies operating inside stores must be located in specific areas, and be at least 10 metres away from areas where alcohol, perishable foods and other substances that may threaten the integrity, purity and conservation of medicines are sold (Mexican Pharmacopoeia Supplement for Establishments, 2010).[83]

Harm to competition. This restriction limits pharmacies to stores where there is enough room for the sale of medicines in addition to alcohol and perishable foods. Small shops with space limitations might be impeded from operating a pharmacy section.

Policymaker's objective. To protect Mexican population against sanitary risks by regulating the sanitary control of establishments. Placing pharmaceutical products together with other products may lead consumers to think that pharmaceutical products are just a mere regular good, which may lead to overconsumption.

However, since medicines are usually packaged, a provision regulating distances between different types of products seems unnecessary since there is no risk of contamination. Also, many pharmacies/stores do not seem to comply with this rule in practice.

Recommendation. The OECD recommends abolishing the provision, as long as a pharmacy only sells packaged products and these are sold in separate areas.

2.3.13.2. Regulation of the size of sale of denatured ethyl alcohol in drugstores

Description of the relevant obstacle. Ethyl alcohol in pharmacies or drugstores aimed at end consumers shall be sold in bottles no bigger than one litre.

Harm to competition. This requirement prevents consumers from buying packages larger than one litre. For some consumers, this may impose higher costs. For example, companies using ethyl alcohol regularly may require larger volumes. This restriction impedes them from buying larger packages that might be cheaper and better fit their needs.

Policymaker's objective. The objective is to regulate sales volumes to end consumers. Even though ethyl alcohol is one of the most popular curative products due to its antiseptic and germicidal characteristics, its addictive power and toxicity can pose a health risk. It is unclear why there is a provision regulating the size of packages for end consumers when ethyl alcohol is not sold as a controlled medicine. If there is a risk associated to the consumption of ethyl alcohol, it is not associated with the size of the package.

Recommendation. Abolish Provision I-d) of the Acuerdo que establece las medidas para la venta y producción de alcohol etílico y metanol and the section of the NOM-138-SSA1-1995 related to the size of packaging of denatured ethyl alcohol.

2.3.13.3. Regulation of the size of ethyl alcohol packaging for health-care units

Description of the relevant obstacle. Denatured ethyl alcohol for the exclusive use of health-care units (e.g. hospitals) may only be sold or marketed in packages of more than 1 litre and not more than 20 litres.

Harm to competition. This provision prevents buyers from acquiring packages bigger than 20 litres. This may impose higher costs. For example, hospitals may find it more efficient to acquire packages larger than 20 litres.

Policymaker's objective. The objective of this provision is to regulate sales volumes of ethyl alcohol to end consumers, including hospitals. Even though ethyl alcohol is one of the most popular curative materials because of its antiseptic and germicidal characteristics, its addictive power and its toxicity can pose a health risk. It is unclear, however, why there is a provision regulating packages size for end consumers when ethyl alcohol is not sold as a controlled medicine. If there is a risk associated to the consumption of ethyl alcohol, it is not associated with the size of the package.

Recommendation. Abolish provision I-e) of the Acuerdo que establece las medidas para la venta y producción de alcohol etílico y metanol and the part of the NOM-138-SSA1-1995 related to the size of the package of denatured ethyl alcohol.

2.3.13.4. Ad honorem status of academic members of the Committee on New Molecules

Description of the relevant obstacle. The work of representatives of academic associations on the Committee on New Molecules shall not be subject to any remuneration. The Committee is defined as being auxiliary and as an independent consultative body (i.e. not paid for by the pharmaceutical industry).

Harm to competition. Members of the Committee might not be sufficiently incentivised to fulfil their task adequately. Market participants consider that sessions of the Committee are not scheduled with the needed frequency (only four sessions are organised each year), which might delay the entry of new products.

Also, according to industry stakeholders, it is problematic that some Committee members are not experts in the matters under discussion, but rather staff of government institutions that later purchase medicines (e.g. IMSS). Some members of the Committee are therefore mostly concerned about ensuring low-cost public procurement, and might block the introduction of new products with high therapeutic value.

Policymaker's objective. The Regulation does not mention any specific objective, but the avoidance of possible conflict of interests may be one.

Industry stakeholders believe that it would not be feasible for Committee members to be remunerated twice (i.e. a remuneration from IMSS and another remuneration for being part of this Committee), as the Ministry of Finance and Public Credit would oppose to the payment of a double salary for a public official.

Similar committees exist in other jurisdictions. For example, in the United States, the Food and Drug Administration's Center for Drug Evaluation and Research (CDER) uses advisory committees to obtain outside advice and opinions from expert advisors so that final agency decisions will have the benefit of wider national expert input.

Recommendation. The OECD recommends amending the provision in order to introduce remuneration of Committee members. This could be paid by the Ministry of

Health and could be indirectly financed by pharmaceutical companies paying for submitting new files to the Committee. The Ministry of Health should guarantee that members of the Committee do not receive direct financial incentives from companies, e.g. through inclusion of sanctions for Committee members who violate conflict of interest rules. Implementation with this recommendation will have to be coordinated with the Ministry of Finance and Public Credit.

2.3.13.5. Unanimity of votes required to amend the internal regulations of the Commission to Define Treatments and Medicines Associated with Diseases Causing Catastrophic Expenses

Description of the relevant obstacle. The Commission to Define Treatments and Medicines Associated with Diseases Causing Catastrophic Expenses (Comisión para Definir Tratamientos y Medicamentos Asociados a Enfermedades que Ocasionan Gastos Catastróficos, CDTMAEOGC), which supports the General Health Council, must vote unanimously to reform its own internal regulations. The Commission is composed of the Secretary of the General Health Council, two representatives of the Ministry of Health, and a representative from each of the following institutions/ministries: IMSS; ISSSTE; the Ministry of National Defence; the Ministry of Navy; the National Autonomous University of Mexico; the National Polytechnic Institute; the National Academy of Medicine; the Mexican Academy of Surgery; the National Association of Universities and Institutions of Higher Education; and the Mexican Health Foundation. All have the right to vote.

Harm to competition. Requiring unanimity hinders the updating of the regulation, such as for the introduction of a new drug to the market, as incumbents may have incentives to influence the committee to maintain the status quo.

Policymaker's objective. The Regulation does not mention any specific objective.

Recommendation. The OECD recommends abolishing the part of the provision related to the unanimity of votes and introduce a provision for (qualified) majority voting.

2.3.13.6. Divergent regulation of time period on notice of ceasing operation

Description of the relevant obstacle. Article 108 of the Reglamento de Insumos para la Salud states that if a holder of a sanitary licence wishes to cease operating an establishment, it must give notice to the Ministry of Health of its decision at least 30 days in advance, unless an unforeseen event or a case of force majeure takes place. However, according to Article 141 of the Reglamento de la Ley General de Salud en Materia de Control Sanitario de Actividades, Establecimientos, Productos y Servicios, the same notice must be provided at least five days in advance. Consequently, there is a contradiction in the regulatory framework, which leaves it unclear when notice needs to be given to the Ministry of Health.

Harm to competition. Criteria on the number of days of notice required is not homogeneous across regulations; this may lead to confusion among market participants.

Policymaker's objective. The objective of these provisions is to protect public health. Chemicals that, if left unregulated, might be used as inputs for illicit drugs should be controlled.

Recommendation. Article 108 of the Reglamento de Insumos para la Salud and Article 141 of the Reglamento de la Ley General de Salud en Materia de Control

Sanitario de Actividades, Establecimientos, Productos y Servicios should be harmonised so that both articles state the same time frame within which notice must be given to the Ministry of Health.

2.4. Horizontal legislation: intellectual property and public procurement for medicines

Most of the horizontal legislation the OECD analysed deals with intellectual property and public procurement. Concerning intellectual property legislation, the OECD does not make any recommendations for the medical sector, except in terms of the linkage problem for generics discussed above. Concerning public procurement in the medical sector, it makes four recommendations for various forms of discrimination in tender processes.

2.4.1. National preference as a tie-breaker in international tenders

Description of the relevant obstacle. The Ley de adquisiciones, arrendamientos y servicios del sector público establishes that there are three types of public tenders:

1. national
2. international under treaty coverage
3. international open.

Type 2 consists of tenders in which both Mexican and foreign suppliers may participate with goods that are either of national origin or from countries with which Mexico has entered into free-trade agreements. For international public-tender bids that are considered "equal", public institutions must prefer those that employ national staff or use nationally produced goods.

Harm to competition. Foreign or Mexican suppliers participating with foreign products might face discrimination. Furthermore, it is unclear how it is determined when circumstances are "equal" as two offers are almost never identical in all features, even with identical prices in a tender procedure that usually involves covered bids.

Policymaker's objective. The objective of this provision is to promote and help the development of national industries.

International comparison. The European Commission generally advocates open international public-procurement markets and grants market access to non-EU countries to its public-procurement markets for certain goods and services. However, some non-EU countries, including the United States, have maintained or introduced protectionist or discriminatory measures in public procurement (i.e. the Buy American Act).

Recommendation. The OECD recommends the following options for the Mexican government:

Option 1) Abolish the part of the provision related to the preference for national staff or nationally produced goods, under equal circumstances.

Option 2) Issue guidelines in order to clarify how to determine when circumstances are "equal" for which case the preference for national products and labour should apply.

Option 3) No recommendation, provided there is no harm to competition. In fact, it is unlikely that two products are ever completely equal (including identical price in tender procedures that usually involve covered bids), so it should be easy to identify when one option is better than another.

2.4.2. Origin requirements to participate in national tenders

Description of the relevant obstacle. Only Mexican nationals or Mexican companies can participate in national tenders, while offered goods (in this case, pharmaceutical products) must have at least 50% national content (ingredients, human labour).

Harm to competition. Foreign pharmaceutical companies and foreign nationals are potentially discriminated against in two ways. First, there is a restriction concerning a bidder's nationality, which includes the nationality of the company. For instance, foreign nationals producing in Mexico are prevented from participating in national tenders even if they have lower prices than their all-Mexican competitors. The provision also restricts the composition of products. A Mexican bidder could not participate with an offer of pharmaceutical products produced either abroad or in Mexico, but with more than 50% foreign ingredients. This could force producers to use more expensive national ingredients.

Policymaker's objective. The objective of this provision is to promote the development of national industry.

International comparison. Many other jurisdictions, such as the United States,[84] have also adapted protectionist procurement measures for the nationality of products.

Recommendation. The OECD recommends the following options for the Mexican government:

Option 1) Abolish the nationality requirement for participants in calls for tenders, while keeping the requirement of the product having at least 50% national content. That would allow foreigners producing in Mexico to also participate in national tenders. In addition, it is recommended that a time limit be introduced for this provision of nationality, giving Mexican producers a transitional period to adapt to having new competitors.

Option 2) Do not change national-tender procedures. As far as possible, however, international tenders should be used.

2.4.3. Preference for more expensive Mexican goods in international tenders

Description of the relevant obstacle. In general, in Mexico, the bidder who meets all the requirements and offers the lowest price wins the tender. However, in the context of international tenders, Mexican goods can have be priced up to 15% higher than the lowest foreign price and yet still be considered as the lowest bid.

Harm to competition. This provision discriminates against foreign producers that might be able to offer a product cheaper than their Mexican competitors. The Mexican consumer will pay higher prices.

Policymaker's objective. The objective of this provision is to promote the development of national industry. However, favouring the Mexican industry in public procurement might be at the expense of the Mexican consumer.

International comparison. Similar provisions exist in other jurisdictions. For instance, in the United States, the Federal Acquisition Regulation implementing the Buy American Act states that: "[i]f there is a domestic offer that is not the low offer, and the restrictions of the Buy American statute apply to the low offer, the contracting officer must determine the reasonableness of the cost of the domestic offer by adding to the price of the low offer, inclusive of duty – (1) 6 percent, if the lowest domestic offer is from a large business concern; or (2) 12 percent, if the lowest domestic offer is from a small

business concern [...] The price of the domestic offer is reasonable if it does not exceed the evaluated price of the low offer after addition of the appropriate evaluation factor."

Recommendation. The OECD recommends abolishing discrimination against foreigners when an international open tender takes place. If the Mexican government wants to promote national industry, it might use national tender procedures or introduce direct subsidies. In addition, it is recommended that a time limit be introduced for this provision to be in force, so that Mexican producers have a transition period during which they can adapt to the new situation and become more competitive.

2.4.4. Preference for micro, small and medium enterprises in Mexican public procurement

Description of the relevant obstacle. Industrial policy aimed at supporting the development of micro, small and medium enterprises (MSME) shall ensure that public procurement is increasingly served by MSME. The objective is that 35% of public procurement shall be served by MSME.

Harm to competition. Low-cost offers from non-MSME participants might not be considered. In particular, larger firms may be discriminated against.

Policymaker's objective. The objective of this provision is to promote the development of MSME. However, according to market sources, the policy seems to be only partially implemented and the participation of MSME in the pharmaceutical sector is currently much lower than 35%, at approximately 8%.

International comparison. Many countries promote MSME development in public procurement, e.g. member states of the European Union,[85] Korea,[86] and the United States.[87]

Recommendation. The OECD recommends the following options for the Mexican government:

Option 1) No recommendation for change as the policy is not binding and only partially applied. Also, helping MSME is a legitimate policymaker objective.

Option 2) Abolish the part of the provision related to target the minimum percentage of public procurement to be awarded to MSME and consider introducing direct subsidies.

2.4.5. Companies under investigation pay for costs of surprise inspections even when no case is proved

Description of the relevant obstacle. Authorities can perform surprise inspections of establishments, such as labs performing tests using measurement instruments, in order to verify compliance with the Law on Metrology and Standardisation. The verified establishment must pay for the expenses of the inspection.

Harm to competition. The company subject to inspection must pay the expenses even if no infringement is found. This may raise costs for some firms and also imposes risks of arbitrary behaviour, for example, if a company is excessively controlled.

Policymaker's objective. The objective of this provision is to protect Mexican population against health risks.

Recommendation. Limit the number of surprise inspections every year to avoid possible abuses. However, additional surprise inspections shall remain possible in case of reasonable suspicion.

Notes

1. The report focuses on North American Industry Classification System (Sistema de Clasificación Industrial de América del Norte, SCIAN) groups 32, 43 and 46, including the relevant subgroups. SCIAN (known as NAICS in the United States and Canada) was developed jointly by the United States, Canada and Mexico to make it easier to compare business statistics between the three countries. Nevertheless, there remain differences between certain SCIAN codes in Mexico and those in the United States and Canada. With respect to the manufacturing of medicines, the main category of pharmaceutical-products manufacturing (SCIAN 32541) is covered, and addresses the following subsectors: inputs for pharmaceutical-industry manufacturing (SCIAN 325411) and pharmaceutical-preparation manufacturing (SCIAN 325412). SCIAN 33911 is excluded in its entirety and includes: manufacture of not-electronic apparatuses for medical and dental use and for laboratories (SCIAN 339111); manufacture of disposable instruments and apparatus for medical use (SCIAN 339112); and the manufacture of ophthalmic items (SCIAN 339113). Inputs for the pharmaceutical industry include alkaloids, antibiotics, hormones and other compounds, and bulk actives, while the manufacture of pharmaceutical preparations includes pharmaceutical and botanical medicines, antiseptics for pharmaceutical use, diagnostic substances, food supplements, plasmas and other blood derivatives. It also includes veterinary medicinal products, but these are not included in this study. Wholesale of pharmaceutical products, allopathic, homeopathic and herbal medicines for human consumption (SCIAN 433110) are covered. Finally, in the retail sector, pharmacies without a minimarket (SCIAN 464111) but which also sell perfumery, hygiene or groceries are considered; pharmacies with a minimarket (SCIAN 464112), which differ from pharmacies without a minimarket as products are organised in sections or small specialised exhibition areas that simplify direct consumer access to the goods, as well as all other stores selling primarily herbal products, homeopathic medicines and food supplements for human consumption (SCIAN 464113). Stores specialised in lenses (SCIAN 464121) and orthopaedic items (SCIAN 464122) are, however, excluded.

2. The General Health Law is the Mexican framework law for the health sector. It establishes the conditions for access to health services and regulates the cooperation between the Mexican Federation and states in matters of public health.

3. When used in this report, the term “pharmaceuticals” covers not only medicines, but also other medical non-durable goods such as bandages, plasters and syringes.

4. There are three different classifications for a medicine with regards to its nature: 1) **Allopathic**, which consists of all substances or mixes of substances of natural or synthetic origin that have a therapeutic, preventive or rehabilitating effect presented under a pharmaceutical form and identified as such owing to their pharmacological activity and to their physical, chemical and biological characteristics, and registered with the Mexican Pharmacopoeia as allopathic medicines. 2) **Homeopathic**, which consists of all substances or mixes of substances of natural or synthetic origin with a therapeutic, preventive or rehabilitating effect, registered in the Mexican Pharmacopoeia or in other countries’ pharmacopoeias or other scientific sources of information. 3) **Herbal**, which includes all the products made with vegetal material or any derivative of this, whose main ingredient is a plant or extracts and tinctures, also its juices, resins, fatty and essential acids presented in a pharmaceutical mode whose therapeutic efficiency and security has been verified scientifically. Another type of

medicine mentioned in the General Health Law is **biotechnological medicine,** whose main characteristic is that it is produced by molecular biotechnology. Regarding the methods of preparation, a medicine can be: 1) **Magisterial**, which refers to medicines prepared according to a formula prescribed by a doctor; 2) **Officinal**, which refers to a combination prepared according to the Mexican Pharmacopeia; 3) **Pharmaceutical speciality,** which are medicines prepared with formulas authorised by the Ministry of Health, in accordance with the chemical-pharmaceutical industry.

5. According to Article 2, Paragraph XIV of the Regulation on Health Inputs, a "generic medicine" is a "pharmaceutical speciality with the same active substance and pharmaceutical form, with the same concentration or power, that uses the same route of administration and that through regulated required tests, has proved that its specifications from the pharmacopeia, dissolutive profiles or its bioavailability or other parameters, depending of the case, are equivalent to the reference medicine". A reference medicine is a medicine that is registered with and approved by the Ministry of Health, is available on the market, and is selected by the Ministry of Health according to criteria of the Mexican Official Standards (Normas Oficiales Mexicanas, NOM). According to NOM-177-SSA1-2013, a dissolutive profile is an experimental determination of the amount of drug in its pharmaceutical form dissolved at different times, under controlled experimental conditions. According to Article 2, Paragraph II of the Regulation on Health Inputs, bioavailability refers to the share of the drug that is absorbed into general circulation after the administration of a medicine, as well as to the time that such absorption takes. According to the General Health Law, in order to be denominated as a generic, medicines must be interchangeable. Interchangeable tests are published in the Federal Official Gazette (Diario Oficial de la Federación, DOF).

6. The Ministry of Economy and the National Chamber of the Pharmaceutical Industry (Cámara Nacional de la Industria Farmacéutica, CANIFARMA) set up a scheme of self-regulation for prices in 1996, which in 2004 was modified by an Addendum to the Consensus Agreement (Adenda al Convenio de Concertación). While the original agreement is public, the Addendum remains confidential, according to the the Law of Transparency and Access to Public Information (Ley Federal de Transparencia y Acceso a la Información Pública).

7. According to Articles 28 and 77 bis 1 of the General Health Law and Article 70 of the Regulation of the General Health Law on Delivery of Healthcare Services (Reglamento de la Ley General de Salud en materia de prestación de servicios de atención médica), there are three levels of medical care. The first level covers outpatient services, which are medical procedures or tests that can be done in a medical centre without an overnight stay. The second level covers outpatient and general inpatient services (i.e. care of patients whose disease requires admission to a hospital) and includes internal medicine, general surgery, gynaecology and obstetrics, paediatrics and geriatrics. Finally, the third level covers outpatient and inpatient services, as well as palliative care to people with specific diseases, with system conditions or diseases affecting specific age groups.

8. The Basic Formulary of Inputs and the Input Catalogue are updated once a year and published in the DOF in order to include, modify or exclude inputs approved by the Basic Formulary and Health Sector Input Catalogue Inter-Institutional Commission (Comisión Interinstitucional del Cuadro Básico y Catálogo de Insumos del Sector Salud). This Commission was specially created to elaborate, update and promote the Basic Formulary and the Input Catalogue; it consists of the Secretary of the General

Health Council as president, as well as representatives of the Ministry of Health, the Mexican Social Security Institute (Instituto Mexicano del Seguro Social, IMSS), the Institute for Social Security and Services for State Workers (Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado, ISSSTE), the Ministry of Navy (Secretaría de Marina, SEMAR), the Ministry of National Defence (Secretaría de la Defensa Nacional, SEDENA), and Petróleos Mexicanos (PEMEX). The Commission's internal regulations allow public-institution providers of health services, academies and suppliers, among others, to request updates to the Basic Formulary or Input Catalogue. The committee in charge of delivering opinions on updates must submit its opinion within a maximum period of 90 days from the receipt of the update request, which may be extended for up to 30 days if more information is required. Requesting an update is free.

9. According to "Comparing access of new drugs in the public health system in Mexico", IMSS and ISSSTE account for 60-70% of the value of the total institutional market, in *Access Point*, www.imshealth.com/files/web/Global/RWE/RWE-Collateral/IMS RWE AccessPoint.pdf.

10. According to Article 50 of the Internal Regulation of the Basic Formulary and Health Sector Input Catalogue Inter-Institutional Commission (Reglamento Interior de la Comisión Interinstitucional del Cuadro Básico y Catálogo de Insumos del Sector Salud).

11. According to Article 32 of the Regulation on Health Inputs (Reglamento de Insumos para la Salud).

12. According to "Censos económicos 2014 Metodología" ("Economic Census 2014 Methodology") issued by the National Institute of Statistics and Geography (Instituto Nacional de Estadística y Geografía, INEGI), an establishment is defined as an economic unit in a single physical location, settled permanently in a place and separated by buildings and fixed installations that acts and uses its resources under the control of a single owner or controlling entity to perform activities related to the production of goods, the sale and purchase of merchandises and the provision of services, profitable or not ("Unidad económica que en una sola ubicación física, asentada en un lugar de manera permanente y delimitada por construcciones e instalaciones fijas, combina acciones y recursos bajo el control de una sola entidad propietaria o controladora para realizar actividades de producción de bienes, compra-venta de mercancías o prestación de servicios; sea con fines de lucro o no"). http://internet.contenidos.inegi.org.mx/contenidos/productos//prod_serv/contenidos/espanol/bvinegi/productos/nueva_estruc/702825075330.pdf.

13. Article 258 of the General Health Law.

14. The Pharmaceutical Academy of Mexico City published the first Mexican Pharmacopoeia in 1846.

15. An Authorised Third Party is a natural or legal person licensed by the Ministry of Health to perform studies related to sanitary procedures, and issue authorisations and opinions regarding the compliance of products with the regulation or Mexican Official Standards. To select Authorised Third Parties, the Ministry of Health issues periodical calls for proposals and forms technical committees of experts, representatives of chambers and associations to decide on the selection.

16. For example, 1) the free-trade agreement, originally between Mexico, Colombia and Venezuela, but since 2006 only between Mexico and Colombia, that came into effect

in 1995 states that medicines, medical equipment and devices, pharmacochemical products and other human, animal- and plant-health supplies that are subject to sanitary registration within the territory of one of the countries shall, where appropriate, be registered, recognised or evaluated on the basis of a single national system. Also, certificates showing compliance with the technical standards and regulations shall be accepted if they have been issued by the competent regulatory authorities of the parties; 2) Article 906 of the 1994 North American Free Trade Agreement between the United States, Mexico and Canada states: "Each Party shall, wherever possible, accept the results of a conformity assessment procedure conducted in the territory of another Party, provided that it is satisfied that the procedure offers an assurance, equivalent to that provided by a procedure it conducts or a procedure conducted in its territory the results of which it accepts, that the relevant good or service complies with the applicable technical regulation or standard adopted or maintained in the Party's territory."

17. Article 195-A of the Federal Fee Law (Ley Federal de Derechos).

18. Last year with available data.

19. "Casa Saba left the Mexican Stock Exchange in May 2013. It sought partnerships to maintain its business; however, it sold the assets of its distribution and wholesale division to two United States Investment Funds", OECD (2014), *Competition Issues in the Distribution of Pharmaceuticals: Contribution from Mexico*, p.8, footnote 9.

20. These statistics include the wholesale of allopathic, homeopathic and herbal medicines for human consumption.

21. INEGI's National Statistical Directory of Economic Units (Directorio Estadístico Nacional de Unidades Económicas, DENUE). This statistic include pharmacies with minimarket (11 030) and without minimarket (45 669), each unit corresponds to a one single establishment.

22. See http://eleconomista.com.mx/industrias/2015/04/08/farmacias-cadena-curan-mas-mexicanos, accessed 6 April 2017, and PharmaBoardroom in collaboration with CANIFARMA (November 2015), *Healthcare Life Sciences & Review*, p.86.

23. COFEPRIS's statistics differ from INEGI's, and put the total of Mexico's pharmacies at more than 28 000 pharmacies.

24. PharmaBoardroom in collaboration with CANIFARMA (November 2015), *Healthcare Life Sciences & Review*, p.86.

25. Pharmaceutical retail include pharmacies without a minimarket (SCIAN 464111), but which also sell perfumery, hygiene or groceries are considered; pharmacies with a minimarket (SCIAN 464112), which differ from pharmacies without a minimarket as products are organised in sections or small specialised exhibition areas that simplify direct consumer access to the goods, as well as all other stores selling primarily herbal products, homeopathic medicines and food supplements for human consumption (SCIAN 464113).

26. Mexicans can belong to more than one public system of health coverage: this explains why the percentages of the population covered by public health insurance total more than 100%. Furthermore, people can take out private health insurance in addition to public health insurance.

27. According to the Mexican Association of Insurance Institutions (Asociación Mexicana de Instituciones de Seguros, AMIS), just under 9.25 million people in Mexico were covered by private health insurance in 2014, accounting for 7.7% of Mexican population.

28. According to a 2015 testimonial of *Transparencia Mexicana*, available at: http://compras.imss.gob.mx/pics/pages/tsociales2014_base/LA_019GYR047_T60_2014_.pdf, accessed on 6 April 2017.

29. According to a Mexican Government press release of 11 January 2017, www.imss.gob.mx/prensa/archivo/201710/009, accessed 25 April 2017. See also, "Acta correspondiente al acto de comunicación de fallo del procedimiento de licitación pública nacional electrónica consolidada número LA-019GYR047-E60-2016", www.imss.gob.mx/sites/all/statics/compraconsolidada/2016/FALLO-E41-2016.zip, accessed 25 April 2017.

30. "Pharmaceuticals" is a category in the International Classification of Health Accounts of Health Care Functions (ICHA-HC) of the OECD System of Health Account. Pharmaceuticals include prescribed medicines, OTC medicines and other non-durable goods such as bandages, plasters and syringes. Non-durable goods account for only a minor share of the overall pharmaceuticals total, typically around 5-10%. Pharmaceuticals are delivered to patients via pharmacies and other retail outlets, but those consumed in other care settings – primarily, the hospital inpatient sector – are excluded. For international comparisons, Purchasing Power Parities (PPPs) are spatial deflators and currency converters that take into account and eliminate the effect of different price levels thus allowing comparisons of spending in a common currency; in this case, US dollars. To measure temporal changes in volume, relevant price indices are used to deflate national spending. Both measure the changes in price for a basket of comparable and representative goods either over time or between countries.

31. Article 24 of the Regulation on Health Inputs states that it is optional for pharmaceutical companies to display a "distinguishing denomination" in labels in the case of generics. Consequently, many generics are sold under a brand name. In 2013, out of all generics sold, branded generics amounted to 44% of the market value and 10% of the market volume.

32. To construct this statistic, PROMÉXICO used information from the Global Trade Atlas, an online database of trade statistics . PROMÉXICO, Unidad de Inteligencia de Negocios (2015), *Industria Farmacéutica y Oportunidades de Negocio en México*, http://mim.promexico.gob.mx/work/models/mim/Resource/99/1/images/091115_PPT_Farmaceutico_esp.pdf..

33. To construct this statistic, PROMÉXICO used information from the Global Trade Atlas, an online database of trade statistics . PROMÉXICO, Unidad de Inteligencia de Negocios (n.d.), *Diagnóstico Sectorial Farmacéutico*, www.promexico.gob.mx/documentos/diagnosticos-sectoriales/farmaceutico.pdf.

34. INEGI computes the Mexican Consumer Price Index on a monthly basis using a Laspeyres formula that weights the following categories of good and services: food, beverages and tobacco; clothing, footwear and accessories; housing costs; furniture, appliances and household goods; health and recreation; and other services. The Consumer Price Index for medicines weights different categories of medicines. Generally, the Laspeyres index estimates the variation in the value of a basket of products under the assumption that the quantities bought of every article composing

the basket are the same as in the base period. When new weights are incorporated to the index, in order to have a historical series, it is necessary to link the newly weighted index to the earlier index series. In order to do this, a linking factor is constructed: the quotient between the index with the earlier weights and the newly weighted index with the new weights, in a given same period (creating an overlap). The factor is then multiplied by the newly weighted index in the periods after the overlapping period.

35. INEGI data from the *2014 National Survey of Household Income and Expenditure* (*Encuesta Nacional de Ingresos y Gastos de los Hogares*, *ENIGH*).

36. Internal-market production is defined as medicine manufacturing minus exports of medicines.

37. The OECD reports 30% as the figure of out-of-pocket medical expenditure in household consumption.

38. Those members include the president of the National Academy of Medicine of Mexico and the president of the Mexican Academy of Surgery.

39. The database is available at www.profeco.gob.mx/precios/canasta/default.aspx.

40. www.canifarma.org.mx, accessed 6 April 2017.

41. www.anafam.org.mx, accessed 6 April 2017.

42. http://anadim.com.mx/PDF/ANADIM_RESULTADOS.pdf, accessed 6 April 2017.

43. www.anadim.com.mx, accessed 6 April 2017.

44. www.amegi.com.mx/conocenos.html, accessed 12 May 2017.

45. http://unefarm.org.mx, accessed 6 April 2017.

46. www.anafarmex.com.mx, accessed 6 April 2017.

47. See, for example, OECD (2017), *Tackling Wasteful Spending on Health*, Chapter 7: Wasting with intention: Fraud, abuse, corruption and other integrity violations in the health sector. http://dx.doi.org/10.1787/9789264266414-en.

48. The last amendment dates to 27 January 2017; see, official website of the Chamber of Deputies, www.diputados.gob.mx/LeyesBiblio/ref/lgs.htm (accessed 2 May 2017).

49. For example, Kesselheim A.S. et al. (2008), *Clinical equivalence of generic and brand name drugs used in cardiovascular disease: a systematic review and meta-analysis*, *JAMA*,300:21, pp.2514-2526.

50. See, Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Medicinal Products for Human Use.

51. Article 94 of Directive 2001/83/EC.

52. See, Department of Health and Human Services (2003), *Office of the Inspector General OIG Compliance Program Guidance for Pharmaceutical Manufacturers*. Fed Register, and Pharmaceutical Research and Manufacturers of America (2008), *PhRMA Code on Interactions with Healthcare Professionals*, Washington, D.C.

53. See, the Food and Drug Administration site, defining generics and illustrating their effects,

www.fda.gov/Drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/default.htm, (accessed 1 June 2017).

54. In Mexico, NOM-177-SSA1-2013 regulates the rules and procedures to show when a medicine is interchangeable. Mexican law states a maximum of 5% of variability for drugs to be considered as interchangeable with the referent product (Article 6.2.8, NOM-177-SSA1-2013).

55. See, for example, Kesselheim A.S., et al. (2008), "Clinical equivalence of generic and brand-name drugs used in cardiovascular disease: a systematic review and meta-analysis", *JAMA*, 300:21, pp. 2514-2526.

56. This is the case of Germany, however, in many other countries, such as the US, the UK, and Sweden, the prices of innovative drugs tend to increase after the entry of generics. In "The Generics Paradox Revisited: Empirical Evidence from Regulated Markets" (2013), Sotiris Vandoros and Panos Kanavos write: "When including all six countries in panel data models, the OECD finds strong evidence that prices of originators increase with generic entry and penetration. When considering each country separately, the OECD finds evidence that the generics paradox is present in the United Kingdom and Sweden, as originator prices increase post-patent expiry. In the Netherlands, prices also increase post-patent expiry, but part of this increase is offset as generic penetration takes place, while in Denmark and Norway generic entry does not affect originator prices. The only country in which generics lead to lower originator prices is Germany" (*Applied Economics*, 45.22, p.3238).

57. See, for example, Grabowski, Henry G., and John M. Vernon (1992), "Brand Loyalty, Entry, and Price Competition in Pharmaceuticals after the 1984 Drug Act", *The Journal of Law & Economics*, 35:2, pp.331-350, www.jstor.org/stable/725543.

58. See, for example, Vandoros, S. and K. Panos (2013), pp.3230-3239.

59. Prescribing with INN is permitted in most EU countries and is mandatory in a few countries (e.g. Estonia since 2010, Portugal and Spain since 2011, and France since 2015). Similarly, pharmacists are allowed to substitute brand-name drugs with generics in a majority of EU countries. While generic substitution is mandatory in some countries (e.g. Denmark, Finland, Spain, Sweden, Italy), the United Kingdom has high generic penetration without any substitution mandate.

60. Definition from drugs.com, www.drugs.com/article/placebo-effect.html, accessed 1 June 2017.

61. Article 6.2.8. of the NOM-177-SSA1-2013 that regulates interchangeability procedures and tests.

62. Directive 2001/83/EC.

63. List at http://siga.impi.gob.mx/newSIGA/content/common/principal.jsf.

64. See, www.fda.gov/drugs/informationondrugs/ucm129662.htm, accessed 1 June 2017.

65. Fourth edition, 2010.

66. Article 31 of the Reglamento de Insumos para la Salud.

67. OECD (2014), *Competition Issues in the Distribution of Pharmaceuticals*, p.21.

68. Conditions for the granting of this authorisation are set in Article 167 of the Reglamento de Insumos para la Salud.

69. Article 76 et seq. of Directive 2001/83/EC.

70. For example, see implementation in Germany, § 52b AMG.

71. For example, see implementation in Germany, § 52b AMG.

72. See following paragraphs citing the World Health Organization and OECD previous work.

73. Article 24 of Directive 2001/83/EC.

74. Draft European Parliament Legislative Resolution on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No. 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (COM(2014)0557 – C8-0142/2014 – 2014/0256(COD)), www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+REPORT+A8-2016-0035+0+DOC+XML+V0//EN.

75. According to Volume 5 of Title 21 of the Code of Federal Regulations, "[c]hanges in the drug substance, drug product, production process, quality controls, equipment, or facilities that have a minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product must be documented by the applicant in the next annual report" and a "supplement must be submitted for any change in the drug substance, drug product, production process, quality controls, equipment, or facilities that has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product".

76. Directive 2010/63/EU on the Protection of animals used for scientific purposes.

77. See World Economic Forum (2015), *Enabling Trade: Unlocking the Potential of Mexico and Vietnam*, www3.weforum.org/docs/WEF_Enabling_Trade_2016.pdf.

78. See, e.g., Erickson, Gary M. (1985), "A Model of Advertising Competition", *Journal of Marketing Research*, 22:3, pp.297-304, www.jstor.org/stable/3151426.

79. Article 88 of Directive 2001/83.

80. See Article 4 of Council Directive 84/450/EEC of 10 September 1984 relating to the Approximation of the laws, regulations and administrative provisions of the Member States concerning misleading advertising.

81. Article 32 of the law forbids misleading or abusive advertising, which is defined as advertising that "refers to features or information related to a good, product or service, which might be true or not, and that induces mistakes or confusion because of its inexact, false, exaggerated, partial, deceptive or biased form".

82. www.uam.mx/difusion/casadeltiempo/29_iv_mar_2010/casa_del_tiempo_eIV_num29_63_67.pdf.

83. Mexican Pharmacopeia (fourth edition), Section II Supplement, p.79.

84. The US Code, Title 41 – Public Contracts, Subtitle IV – Miscellaneous, Chapter 83 – Buy American states that "[o]nly unmanufactured articles, materials, and supplies that have been mined or produced in the United States, and only manufactured articles, materials, and supplies that have been manufactured in the United States substantially all from articles, materials, or supplies mined, produced, or manufactured in the

United States shall be acquired for public use unless the head of the department or independent establishment concerned determines their acquisition to be inconsistent with the public interest or their cost to be unreasonable." According to the same law, materials shall be considered to be mined or produced in the United States if the cost of the national products used in such materials constitutes more than 50% of the cost of all the products used in such materials.

85. See Directive 2014/24/EU, e.g. Germany § 97 Paragraph 4, Act against Restraints of Competition.

86. For instance, in Korea, according to Article 4 of the Act on Facilitation of Purchase of Small and Medium Enterprise-Manufactured products and support for development of their markets: "[w]hen the heads of public institutions intend to conclude contracts for the procurement of goods [...], they shall provide small and business proprietors with increased opportunities for receiving orders."

87. In the United States, Subpart 19.7 of the Small Business Subcontracting Program of the Federal Acquisition Regulation states that any contractor must agree in the contract that small businesses will have the maximum practicable opportunity to participate in contract performance consistent with its efficient performance.

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Annex 2.A1

Summary of quantifications for the medicine sector

If this set of OECD recommendations[1] for the medicine sector is fully implemented, the benefit to consumers is estimated to range between MXN 10 177.1 million and MXN 43 813.8 million. A summary of the estimated benefit to consumers is shown in Table 2.A1.1.

It would not be methodologically appropriate to add up consumer benefits that result from implementing recommendations A1 and A2 because it would involve double counting. Once A2 has been implemented, the additional benefit from implementing A1 should be discounted. The OECD team has therefore constructed two cases to show two possible discounts. Case 1 consists of discounting by 20% the benefit from A1, while Case 2 consists of discounting it by 50%.[2]

Table 2.A1.1. **Estimated benefit**

Recommendation	Benefit (MXN, millions)	
	Lower end	Upper end
A1. Removal of incentives to doctors	7 743.1	7 743.1
A2. Substitution at pharmacy / doctors only prescribe INN drugs	6 177.4	34 544.8
A3. Implementation of obligation for producers to supply every full-line wholesaler in the private market	128.1	3 074.6
A4. Introduction of only one renewal of the sanitary registry, with subsequent random controls*	4.8	4.8

* This recommendation was not taken into account in the estimation of total consumer benefit shown in Table 2.A1.2.

Source: OECD analysis.

Table 2.A1.2. **Total consumer benefit**

Recommendation	Total consumer benefit (MXN, millions)	
	Lower end	Upper end
Case 1	12 500	43 813.8
Case 2	10 177.1	41 490.9

Source: OECD analysis.

Notes

1. Annex 2.A2, 2.A3 and 2.A4.
2. In cases where substitution at pharmacies takes place and incentivisation is not proscribed, doctors prescribing branded medicines would not have any effect unless they specify that substitution is not allowed. However, due to incentivisation, doctors may overprescribe patented medicines. Hence, even if it seems that by implementing recommendation A2, recommendation A1 does not have any impact, it prevents overprescription of medicines or the "substitution not allowed" specification in prescriptions.

Annex 2.A2

Incentives to doctors

If this OECD recommendation is fully implemented, the benefit is estimated to be MXN 7 743.1 million.

Description and harm

Mexico currently has no law regulating the benefits pharmaceutical companies can provide to doctors (such as conference participation or speaker engagements). There is, however, an ethics code issued by the Council of Ethics and Transparency of the Mexican Pharmaceutical Industry (Consejo de Ética y Transparencia de la Industria Farmacéutica, CETIFARMA), which belongs to CANIFARMA.

This ethics code, which addresses financial incentives, only applies, however, to CANIFARMA members (87% of all pharmaceutical companies). According to the CETIFARMA document, providing financial incentives of significant value to doctors is forbidden. Infringement of the code is subject to reprimand, financial penalties (no specific amounts are detailed, however), and temporary or definitive suspension of the rights as a CANIFARMA affiliate.

A lack of binding governmental regulation in this field may hinder competition among similar products. Some doctors receive benefits from pharmaceutical companies with the result that they may prefer those companies' products rather than those they might otherwise regard as best clinically suited or most economic for the patient.

Recommendation

Issue a binding regulation determining the exact conditions under which financial advantages or benefits of significant value to doctors can be granted. This regulation should contain sanctions in case of infringement of the conditions. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001, as well as the CETIFARMA ethics code, might be used as a starting point.

Estimates of the benefits arising from the recommendation

Methodology

Effects of implementing a provision and/or regulation that prohibits supplying financial advantages or benefits of significant value to doctors, by estimating the consumer benefit if all doctors behave the same way (i.e. receiving no payments from the pharmaceutical industry).

There is no data publicly available in Mexico of the percentage of doctors who receive payments from the pharmaceutical industry. However, in the United States, data revealing the payments doctors receive from pharmaceutical companies is available

online. Using available US data, Jones and Ornstein (2016), showed the relationship between industry payments and prescription of branded medicines (Jones, Ryan Grochowski & Charles Ornstein, 2016).

The main results from that study, using a sample of doctors with more than 1 000 claim counts, are shown in Table 2.A2.1.

Table 2.A2.1. **Prescription patterns of doctors receiving incentives versus non-incentivised doctors**

	Doctors with >1 000 claim count	Subset who received an industry payment	Subset who did not received an industry payment	Percentage who received a payment	Percentage who did not receive a payment	Mean brand-name prescribing rate (no payments)	Mean brand-name prescribing rate (payments)
Family medicine	65 651	46 753	18 898	71.21%	28.79%	18.70%	20.20%
Internal medicine	51 607	36 329	15 278	70.40%	29.60%	19.80%	22.00%
Cardiology medicine	13 817	12 308	1 509	89.08%	10.92%	19.20%	21.60%
Psychiatry medicine	11 052	8 650	2 402	78.27%	21.73%	13.60%	15.60%
Ophthalmology medicine	8 196	7 117	1 079	86.84%	13.16%	46.40%	56.90%
Total	**150 323**	**111 157**	**39 166**	**73.95%**	**26.05%**	**19.6%**	**22.94%**

Source: Jones and Ornstein (2016), *Matching Industry Payments to Medicare Prescribing Patterns: An* Analysis and OECD Analysis.

Current situation

$$Private\ Market\ Value = X\ (\%Doctor\ with\ incentives * \%\ BNM + \%Doctor\ without\ incentives * \%\ BNM) + 0.2X\ (\%Doctor\ with\ incentives * \%\ generics + \%Doctor\ without\ incentives * \%\ generics)$$

where X is the private market value of medicines if all final consumers buy brand name medicines (BNM) and 0.2X is the private market value of medicines if all final consumers buy generics, since the implicit price ratio of generic medicines to brand-name medicines is 0.2,

$$MXN\ 147\ 715.91\ million = X\ (73.95\% * 22.94\% + 26.05\% * 19.6\%) + 0.2X\ (73.95\% * 77.06\% + 26.05\% * 80.4\%)$$

$$MXN\ 147\ 715.91\ million = X * (22.07\%) + 0.2X * (77.93\%)$$

$$X = MXN\ 392\ 312\ million$$

and MXN 78 462.4 million is the private market value of medicines if all final consumers buy generics.

With a change in regulation (i.e. if doctors no longer receive incentives) it is assumed that all doctors would prescribe the same share of generics and brand-name medicines with the same frequency as currently non-incentivised doctors do:

$$Private\ Market\ Value = X\ (\%Doctor\ without\ incentives * \%\ BNM) + 0.2X\ (\%Doctor\ without\ incentives * \%\ generics)$$

$$Private\ Market\ Value = MXN\ 392\ 312\ million\ (19.6\%) + 0.2\ (MXN\ 392\ 312\ million)\ (80.4\%)$$

$$Private\ Market\ Value = \ MXN\ 139\ 972.8\ million$$

Therefore, savings (i.e. consumer benefit) that final consumers would receive if all doctors were not incentivised are MXN 7 743.1 million.

References

Jones, Ryan Grochowski & Charles Ornstein (2016), *Matching Industry Payments to Medicare Prescribing Patterns: An Analysis,* https://static.propublica.org/projects/d4d/20160317-matching-industry-payments.pdf?22.

Annex 2.A3

Substitution of prescribed medicines with generics

If this OECD recommendation is fully implemented, the benefit to consumers is estimated to range between MXN 6 177.4 million and MXN 34 544.8 million.

Description and harm

When prescribing a medicine, doctors can either prescribe the generic name or the generic and distinctive designations (or brand name) jointly. The former is known as an International Nonproprietary Name or INN, and defined by the World Health Organization as a unique name that is globally recognized and public property. The latter is a mix of generic drug and brand name: for example, salbutamol and "Ventolin"; ibuprofen and "Advil"; or paracetamol and "Tylenol". When doctors prescribe the distinctive denomination, pharmacists must comply with that wish; the medicine can only be replaced when the doctor expressly authorises it.

Consumers are locked into buying a branded medicine if it is prescribed by the doctor. Generics may therefore face a competitive disadvantage if doctors tend to prefer certain branded medicines and do not include generics in their prescriptions, or authorise the substitution of the branded product.

Recommendation

The OECD recommends the following options for the Mexican government:

Option 1) Amend the provision in order to oblige pharmacists to inform patients about the cheapest available generic and allow the substitution of prescribed medicines with this generic when the patient agrees, unless the doctor has specified "substitution not allowed" in the prescription (this might be necessary if certain patients do not react well to generic substitutes of a certain medicine). The OECD recommends making the substitution optional, not mandatory because most purchases in Mexico are out-of-pocket spending by customers and that customers must be able to purchase the medicine they perceive to be best (placebo effect).

Option 2) Introduce a provision that requires doctors to prescribe INN medicines (i.e. the active substance).

Either option will bring the same consumer benefit.

Estimates of the benefits arising from the recommendation

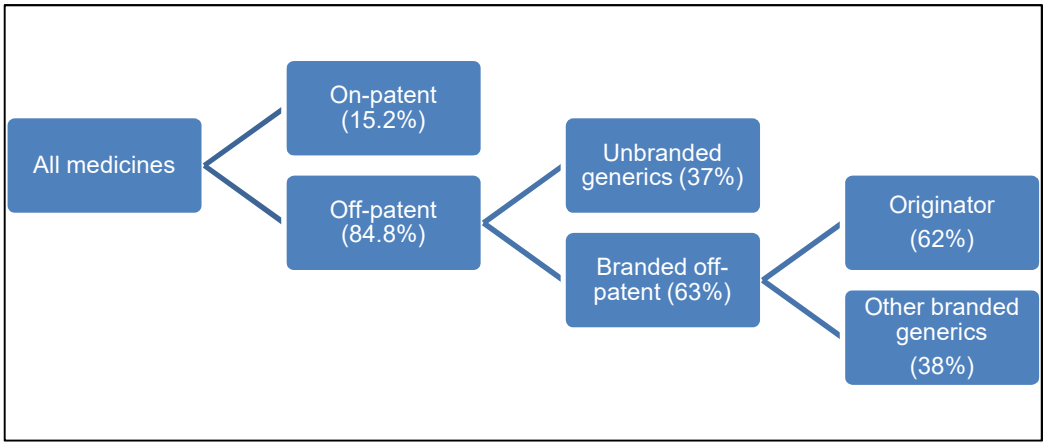
Methodology

To calculate the consumer benefit of allowing substitution of prescribed medicines with generics or requiring doctors to only prescribe medicines on INN we followed two different methodologies. Given the limited time and resources available, we relied heavily

on existing market research and a detailed bibliographical review of academic research from the relevant experience in this market from Mexico and other OECD countries.

According to PharmaBoardroom (PharmaBoardroom, 2015), the Mexican market value for medicines in 2012 was MXN 190 181 million. According to Funsalud (Fundación Mexicana para la Salud, 2013), out of this value, on-patent medicines represented 15.2% market share, whereas off-patent medicines 84.8%. Out of the later, branded off-patent medicines (i.e. originators plus branded generics) accounted for 63% market share of the off-patent medicines, hence unbranded generics (including private labelled generics which are generics labelled with the name of the pharmacy chain or laboratory, not particularly advertised and whose prices are very close to unlabelled generics) for 37% market share. The final classification of interest is between originator and other branded off-patent medicines. The value market share (within the branded off-patent category) of originator medicines was approximately 62%, while branded generics accounted for 38%. Figure 2.A3.1 summarises this information.

Figure 2.A3.1. **Value market shares of different types of medicines in Mexico**



Source: OECD analysis.

The pharmaceutical market in Mexico has traditionally been a physician-driven market, as many E.U. markets, such as France, Spain, Italy or Germany, and in contrast to the more pharmacy-driven markets, such as the US, Canada or the UK (Danzon and Furukawa, 2011). In physician-driven markets where pharmacists are either not authorised or incentivised to substitute towards the cheapest alternative, generics penetration is significantly lower (for instance, in 2009, penetration varied from 60% in the UK to 89% in the US in the pharmacy-driven markets compared to a range from 22% in Spain to 50% in France in the physician-driven countries, with Mexico around 30%). Moreover, in countries with a weaker institutional framework and enforcement of law where generic quality is uncertain, brand plays a much more important role. For example, whereas the vast majority of generics are unbranded in countries such as the US, the UK, France or Germany, the opposite is true for countries such as Brazil or Mexico, where most sales are generated by branded generics.[1] Competition to build brand equity undermines competition on price and as a result branded generics keep prices relatively high.

OECD's recommendation essentially focuses on the potential savings that could be achieved by intensifying competition within the off-patent category. Unbranded generics are not considered for our estimates since OECD's recommendation would not result in a price reduction in this category as the current legislation does only restrict substitution of prescriptions of a certain brand.

The first methodology utilises the following formula to estimate the consumer benefit of allowing substitution of prescribed medicines with generics at the pharmacy (OECD, 2015: 100):

$$CB = \left(\rho + \frac{\varepsilon}{2}\rho^2\right) R$$

Where:

CB: standard measure of consumer benefit

ρ: absolute value of percentage change in price related to restriction

R: sector revenue

ε: absolute value of price elasticity of demand.

The OECD assumes the value of price elasticity of demand to be zero, as we make the simplifying assumption that demand is driven by doctors' prescriptions and it is not responsive to price in the short run (OECD, 2017: 197). This restriction concerns categories D1[2] and D3[3] of the Competition Assessment Toolkit. ρ is assumed to take either a value of 0.16 (i.e. the minimum ρ between D1 and D3) or a value of 0.32 (i.e. the maximum ρ between D1 and D3) (Ennis, 2017). Following our previous market description (see Figure 2.A3.1).

Taking account of the the so called "generic paradox" (i.e. originator prices do not decrease after the entry of generics),[4] this scenario assumes that originator prices do not change in the short run while branded generics do. Thus, R is considered to be equal to the 38% of the branded off-patent medicines or MXN 38 608.87 million.

Hence, the computation of the consumer benefit of allowing substitution of prescribed medicines with generics is estimated to be between of MXN 6 177.42 million (lower bound) and MXN 12 354.84 million (upper bound).

The second methodology to calculate consumer benefits borrows directly from the work of Danzon and Furukawa (2011). Using very detailed data from 10 countries (US, UK, Germany, France, Spain, Italy, Japan, Canada, Brazil and Mexico) over the period 1998-2009 they examine the performance of generic markets at the level of drug presentation (molecule-form-strength) as this is where pharmacy substitution can legally take place. They estimate a four equation model: for any generic entry; number of generic firms, conditional on entry; generic or originator price; and generic volume share. They run separate regressions for each country, allowing all coefficients to vary by country.

Focusing on their estimated results on prices, the authors show that the main driving force of lowering prices is the entry and number of unbranded generic manufacturers (see Danzon and Furukawa [2011], Table 5). Finally, based on the whole set of results from all four equations, they calculate the potential payer savings based on the generic-originator price difference and on the share of prescriptions that are dispensed generically. For our purposes, we utilise the total percentage savings that basically measures how much lower expenditure would have been if all branded off-patent medicines (i.e. originator medicines plus branded generics) were sold as unbranded

generics. To calculate the consumer benefits in this case we multiply the total percent savings with the revenues from branded off-patent medicines:

$$CB = \frac{(P^O - P^G)Q^G}{(P^O Q^G + P^O Q^O)} R$$

where:

CB: measure of consumer benefit

Q : denotes units, superscripts O and G denote originator and generic, respectively

P : denotes price, superscripts O and G denote originator and generic, respectively

R : revenue of originator medicines

The OECD team assumes that the ratio is equal to either 0.340 (see Danzon and Furukawa [2011], Table 8) which the latest estimate based on the years 2006-2009 for Mexico or 0.166 which is the average savings over the whole period (1998-2009). Based on our previous market description (see Figure 2.A3.1), R is considered to be equal to the 63% of the off-patent medicines or MXN 101 602.3 million.

The computation of consumer benefit of allowing substitution of branded off-patent medicines with generics is estimated to be between of MXN 16 899.85 million (lower bound) and MXN 34 544.78 million (upper bound).

Therefore, both methods seem to indicate significant consumer benefits from the enhanced competition in this market. Given the history and the current state of the Mexico market, OECD's recommendations are more likely to affect first the competition between branded generics and unbranded medicines (first methodology). More intense competition among generics will also affect the originator medicines prices (second methodology), but this is more likely in the medium to long run. The lesson from other OECD countries (mostly European) is that complementary policies, such as reference pricing systems, are particularly effective in bringing down originator prices (Kanavos, 2014: 224-241).

Notes

1. See Figure 7 in Danzon and Furukawa (2011).
2. "Limits the ability of consumers to decide from whom they purchase"
3. "A restriction that fundamentally changes information required by buyers to shop effectively"
4. For instance, Frank and Salkever (1997) reported that the entry of an additional generic seller is associated with an average 0.7% increase in the price of the originator medicine, Regan (2008) reported 1% and Danzon and Furukawa (2011) stated that "originator prices are generally stable in response to generic entry, but at different levels reflecting different regulatory regimes".

References

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Annex 2.A4

Direct sales

If an obligation for medicine producers to supply all full-line wholesalers in the private market would be implemented, the benefit is estimated to be between MXN 128.1 million and MXN 3 074.6 million.

Description and harm

Wholesale and retail of medicines and other health products, narcotics, psychotropic substances, and products containing narcotic or psychotropic substances requires a sanitary authorisation (i.e. a licence). This licence granted to pharmaceutical companies is not limited to the manufacture of medicines. The OECD team did not find any provision prohibiting direct selling by pharmaceutical companies to pharmacies.

In practice, however, many pharmaceutical companies in Mexico refuse to sell directly to pharmacies, even to big pharmacy chains, preferring to sell through wholesalers. It is common practice for pharmaceutical companies to sign exclusive contracts with one distributor. Wholesalers therefore often become the only channel through which to commercialise a certain medicine.

For large retailers (i.e. pharmacy chains), this purchasing from a wholesaler imposes an unnecessary cost, as they have to pay an extra margin to wholesalers instead of acquiring the products directly from the producers. Also, market participants at retail level complain that many medicines are distributed by only one wholesaler and there is no, or only very limited intra-brand, competition for many medicines in Mexico.

The described problem concerns the private market as the public authorities generally purchase medicines via public tenders.

Recommendation

The OECD recommends that Mexico considers introducing an obligation for medicine producers to supply all full-line wholesalers in the private market, which would have the aim to allowing new wholesalers to compete. Before moving forward with such a measure however it is recommended that a study in coordination with the relevant authorities assesses the impact on the market of introducing such an obligation, whose purpose would be to allow new wholesalers to compete in the concentrated Mexican wholesale market and increase intra-brand competition. However, as this proposed recommendation would interfere with contractual freedom, it should only be implemented if such study would demonstrate that other measures to strengthen intrabrand competition do not lead to any results.

Estimates of the benefits arising from the recommendation

Methodology

Effects of implementing an obligation for producers to supply every full-line wholesaler in the private market, which will mainly impact pharmacy chains' income.

Large pharmacy chains' income in 2014 was MXN 51 243 million; if these pharmacies stopped purchasing medicines through wholesaler distributors and began to purchase directly from pharmaceutical companies, they would not incur payments to wholesaler distributors (i.e. wholesalers' margin, which is a share of the final price or income), but would still allocate resources to their distribution networks. The OECD presents four different scenarios for wholesalers' average margins (5%, 10%, 20% and 30%) and assumes that by creating their own distribution system, big pharmacy chains will spend between 80% and 95% of the wholesaler distributors' margin.

Three scenarios for savings rates are presented in Table 2.A4.1: 5%, 10% and 20%.

Table 2.A4.1. **Scenarios for large pharmacy chains' savings (MXN, millions)**

		Wholesalers' average margin			
		5%	**10%**	**20%**	**30%**
Savings rate	5%	128.11	256.22	512.43	768.65
	10%	256.22	512.43	1 024.86	1 537.29
	20%	512.43	1 024.86	2 049.72	3 074.58

Source: OECD analysis.

Annex 2.A5

Sanitary-registry renewal

If this OECD recommendation is fully implemented, the benefit to consumers is estimated to amount to MXN 4.8 million.

Description and harm

Sanitary registries need to be renewed every five years. According to Article 195-A of the Federal Government Fees Law, for a sanitary-registry renewal, applicants must pay 75% of the new sanitary-registry fee (the sanitary-registry fee for generics is MXN 71 334.41 and for new-molecule medicines MXN 127 549.79).

Requiring that the sanitary registry is renewed every five years imposes an extra cost on firms. The costs can be quite significant for producers often marketing hundreds of products.

Recommendation

Renew the sanitary registry only once after five years; after that time, it should become permanent. The OECD agrees with COFEPRIS that such a change in system should only be implemented after the Mexican control and supervision system has been significantly improved. This would require increasing the frequency of on-site controls; introducing large fines if pharmaceutical companies do not report changes in a medicine to COFEPRIS in time; and granting adequate resources to COFEPRIS to fulfil this task.

Estimates of the benefits arising from the recommendation

Methodology

Effects from changing the sanitary registry renewal to annual controls.

Last year, sanitary registries of 573 allopathic medicines, 34 herbal medicines, 42 homeopathic medicines and 34 vitamin medicines were renewed. For every sanitary registry renewal, applicants pay 75% of the original fee, which is MXN 71 334.41 for generics and MXN 127 549.79 for new molecule medicines if medicines are allopathic. If medicines are herbal, homeopathic or vitamins, applicants shall pay 75% of the original fee, which is MXN 16 962.82.

If pharmaceutical companies were no longer required to apply for a sanitary registry renewal, savings for firms every five years will be MXN 32 055 395.35 (assuming that all applicants obtained sanitary registries for generics); annually, they will be MXN 6 411 079.07; assuming that annual controls will cost MXN 2 322.61 (the fee stated by the Federal Fee Law for a sanitary compliance visit), total annual costs will be MXN 1 586 342.63. The net savings from changing sanitary-registry renewal to annual controls are therefore calculated at MXN 4 824 736.44 every year.

This estimation does not take into account the internal savings (e.g. preparation of documents) that pharmaceutical companies will experience if they do not have to repeat every five years all the required tests when the sanitary registry was first granted. Also, the annual costs related to the annual revisions might be underestimated. A significant improvement of the Mexican control and supervision system will bring additional costs, which will probably have to be financed by the pharmaceutical companies.